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Vibrotactile Postural Control in Patients that have Sit-to-Stand Balance Deficit and Fall

By Karen L. Hastings Atkins

United States Army Aeromedical Research Laboratory
Warfighter Performance and Health Division

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14. Abstract

Method: The cohort is a prospective case/control study using Pearson *r*, paired sample *t*-test, multivariate analysis of variance (MANOVA), and Wilcoxon signed rank analysis to determine the relationship between standard of care physical therapy plus vibrotactile force platform device treatment and standard of care physical therapy only. The Berg Balance Scale (BBS), Dynamic Gait Index, functional independence measure-motor (FIM-Motor), NeuroCom Sit-to-Stand normative ratios, NeuroCom Comprehensive Report, and self-reported falls quantify change over time with repeated measure study design. **Results:** The study found a significant beneficial effect in the device intervention group which realized 39.5/56 to 51.2/56 mean score increase in Berg Balance Score, increase in mean Dynamic Gait Index from 11.7/24 to 19.8/24, mean increase in FIM-Motor from 16.4/21 to 19.5/21 and decrease in self-report falls from 4 to 2 by intervention Day 14. These findings encourage further investigation of vibrotactile force platform devices.

Forward

I am pleased to introduce the academic dissertation of Dr. Karen Atkins to the wider government technical information community. Dr. Atkins' dissertation represents an important contribution to our knowledge concerning balance rehabilitation during physical therapy. This work comprises the most detailed assessment to date of the efficacy of tactile sway feedback to augment balance rehabilitation. The concept of using tactile feedback as an aid for patients with balance dysfunction was derived originally from the Department of Defence (DOD) development of tactile devices for pilots to maintain orientation and improve situation awareness[1]. Dr. Atkins expanded the DOD's work in a new direction by initiating the use of the tactor hardware and orientation algorithms developed by DOD[2] to perform the extensive balance cueing investigations described in the dissertation. The balance applications of her work partly grew out of a recent U.S. Army Medical Research and Materiel Command (USAMRMC) project, "Using Tactile Cuing Systems in Traumatic brain Injury (TBI) Patient Mental and Physical Rehabilitation," of which I was the Principal Investigator. The objective of this U.S. Army Aeromedical Research Laboratory (USAARL) project was to solicit initial expert input concerning the likely feasibility of tactile cueing as a compensatory strategy for patients diagnosed with TBI. Meetings were held with physical therapists such as Dr. Atkins, as well as other experts from Army, Navy, and Marine Corps, who considered the likely efficacy and the most appropriate application of tactile cueing. This first round of input has been incorporated into subsequent (ongoing) USAARL efforts in testing and rehabilitation, as well as DOD Small Business Innovative Research (SBIR) efforts to develop the next generation of cueing devices and assist their transition for widespread use. One of these SBIRs is now a Phase I project with Dr. Atkins as the Principal Investigator. Finally, a series of workshops has been initiated by the Coalition Warfare Program, Office of Secretary of Defence, which will bring together a wider range of international subject matter experts to finalize the best practices for clinical implementation of the technology for testing, rehabilitation, and assistance. In my opinion, this growing body of work is a great example of government, academia, and industry working together to help improve people's lives.

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Research Scientist, USAARL,
Flight Surgeon, Navy Medical Corps (retired)
Fort Rucker, AL, 7 July, 2010

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[1] Rupert A. H. (2000). Tactile situation awareness system: proprioceptive protheses for sensory deficiencies. *Aviation, Space, and Environmental Medicine*, *71*, A92-99.

[2] McGrath, B. J., Estrada, A., Braithwaite, M. G., Raj, A. K., & Rupert, A. H. (2004). *Tactile situation awareness systems flight demonstration final report*. (Report No. 2004-10). Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. (Defense Technical Information Center No. ADA422198).

VIBROTACTILE POSTURAL CONTROL IN PATIENTS THAT HAVE SIT-TO-STAND BALANCE DEFICIT AND FALL

by

Karen L. Hastings Atkins

A dissertation proposal submitted in partial fulfillment of the requirements for the degree of DOCTOR OF PHILOSOPHY

Nova Southeastern University
College of Allied Health and Nursing
Physical Therapy Department

2010

We hereby certify that this dissertation, submitted by Karen L. Hastings Atkins, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the dissertation requirement for the degree of Doctor of Philosophy.

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January 2010

Purpose: Vibrotactile displays have been found to be beneficial in improving balance test scores that correlate with a decrease in fall rate in laboratory studies. Investigations of these devices have been limited to upright stance and have not been done in clinical settings. Furthermore, transitional movements facilitated by vibrotactile displays, such as forward lean and rise found in sit-to-stand, have not been investigated. A prospective study investigated the relationship between force platform vibrotactile intervention and balance test scores, sit-to-stand and falls in subjects with abnormal NeuroCom Sit-to-Stand test results and 2 or more self-reported falls within the last 6 months. **Subjects:** Subjects included 30 community-dwelling adults, aged 60 to 79 years, 10 as off-site controls, 10 as on-site controls, and 10 as on-site device intervention subjects. **Method:** The cohort is a prospective case/control study using Pearson *r*, paired sample *t*-test, multivariate analysis of variance (M)ANOVA), and Wilcoxon signed rank analysis to determine the relationship between standard of care physical therapy plus vibrotactile force platform device treatment and standard of care physical therapy only. The Berg Balance Scale (BBS), Dynamic Gait Index, functional independence measure-motor (FIM-Motor), NeuroCom Sit-to-Stand normative ratios, NeuroCom Comprehensive Report, and self-reported falls quantify change over time with repeated measure study design. **Results:** The study found a significant beneficial effect in the device intervention group which realized 39.5/56 to 51.2/56 mean score increase in Berg Balance Score, increase in mean Dynamic Gait Index from 11.7/24 to 19.8/24, mean increase in FIM-Motor from 16.4/21 to 19.5/21 and decrease in self-report falls from 4 to 2 by intervention Day 14. These findings encourage further investigation of vibrotactile force platform devices.

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CHAPTER I: INTRODUCTION

Introduction

The desire of most people is to remain independent. The growth in senior populations, with rising health care costs related to the cost of caregiving to patients with limited independence and with injuries sustained from a fall, makes finding ways to promote independence and reduce the number of falls, especially in senior populations, of paramount importance. Current meta analyses find that existing balance-and-falls intervention strategies are only marginally successful.[1,2,3] However, the exercise-alone interventions are more effective compared with multifactorial ones.[4] New intervention strategies are needed to improve mobility and balance and to decrease falls.

New technology may improve postural control and balance skills that are necessary for patients to remain independent. The vibrotactile force platform device is a system for the training of patients with balance deficit and/or movement disorders by providing sway data to the patient and a set of standardized and/or custom functional activities that include real-time sensory enrichment via vibrotactile display feedback. The device is a tool that may aid therapists when teaching patients to learn or relearn balance and movement skills.

The Importance of Transitional Movements

Sit-to-stand is an important skill, a transitional movement that is considered one of the

most mechanically demanding of functional daily activities and is essential for ambulation.[5,6] Standing up, standing, and sitting are essential activity of daily living functions and prerequisites for gait.[7] Inability to go from sit-to-stand impairs activities of daily living, which can lead to loss of independence, institutionalization, and falls that result in injury, including death.[8] Usually physical therapists attempt to normalize physical deficits at the level of impairment by achieving physiologic change. Hence, sit-to-stand studies are generally directed at the level of the impairment and not at the level of skill.[9] For example, lower extremity strength, hip-knee-ankle joint flexibility, or joint replacement technique may be the focus of rehabilitation, yet the intervention goal is to normalize sit-to-stand. This study acknowledges the multifactorial impact of physiology on balance, but quantifies skill sets associated with postural control. Postural control of static and dynamic sway is a basic skill associated with balance and is necessary for all activities of daily living. Accordingly, postural control of sway necessary for balance uses orientation referenced to gravity. The vibrotactile cueing delivered by this force platform device references gravity and delivers enriched data to be used for conscious decisions regarding postural control.

The Importance of Equilibrium

Postural imbalance and disequilibrium, the latter of which couples both dizziness and postural imbalance, can be debilitating by limiting activities of daily living and increasing the potential for falls. A balance control disorder is the consequence of sensory and/or motor dysfunction, resulting in impaired equilibrium control.[10,11] Disequilibrium and/or imbalance is the precursor to falling. Imbalance becomes a concern when volitional

activity, such as the ability to get out of a chair independently, or staggering and drifting when walking, becomes impaired. Limited activities of daily living and social interaction are often the result of imbalance and disequilibrium. Consequently, falls that do not lead to injury in our senior population often begin a downward spiral related to fear of falling that leads to inactivity, decreased levels of fitness, and decreased balance, resulting in loss of independence in activities of daily living.[12]

Force platform vibrotactile technology may be of value to patients with disequilibrium resulting from multifactor physiologic system decline, as seen in older populations with abnormal sit-to-stand parameters who also report falls. The relevance of research of a force platform vibrotactile device for physical therapists is far-reaching. Not only may the technology investigated in this study be found to be beneficial in increasing the level of independence and in intervening in falls, but other like types of technology may be recognized for their rehabilitation evaluation and intervention potential as well. Force platform vibrotactile technology offers an additional strategy to improve function directed at the patients' level of skill. A paradigm shift may occur, resulting in the general use of technology, particularly dynamic feedback assistive devices for balance: theoretical frameworks within rehabilitation treatment rationales could change.

Overview

The force platform vibrotactile device exploits center-of-pressure (COP) referenced displays to enrich sensory data necessary for successful balance. Interestingly, our

National Aeronautics and Space Administration (NASA) space program is developing a similar vibrotactile inertia device, a gyroscope-like inertia sensor, that measures tilt and rate of tilt, for astronauts to use when walking on Mars.[13] To date, over 11 million dollars has been spent through NASA and National Institutes of Health (NIH) grants to bring the inertia (accelerometer) sensor balance vest forward.[14,15-18] The force platform vibrotactile device is similar to the NASA device, but with COP data representing center-of-gravity (COG) data gathered from pressure on a force platform rather than from an accelerometer.

Theoretical Framework

Referencing balance and postural control to gravity is a feedback model that allows for variables in both the individual and in mobility tasks. Stable balance evolves from sensory feedback during static and/or small movement postural control. Supporting postural points of instability with momentum and trajectory cueing to points of stability is a feedback approach to equilibrium. Feedforward movement uses feedback postural control to increase limits of stability. This multivariant model is in contrast to the single-variant model currently guiding traditional physical therapy fall intervention programs. A single-variant model would, for example, associate the knee joint angle to an optimal ankle joint angle to achieve a weight-bearing task. An analogy for a single-variant model would be shooting a rocket towards a planet, with each successive attempt going higher and higher, but without considering gravitational rotation, necessitating a curved trajectory, periods of momentum achieved from force, and periods of deceleration when the target is near.[19] Multivariant models demonstrate that small differences in initial

equilibrium, when referred to COG, trajectory, momentum, and cadence, can result in large variations of task outcome.

Vibrotactile Theoretical Framework

The sense of touch is intrinsically linked with the neuromotor channel, both at the reflex and at higher cognitive regions, which makes it uniquely tied to orientation and localization. It is known that the human sensory system is capable of adaptation.[20,21] For example, a fixed reference such as a fingertip, when provided to a patient who has been blindfolded, has been shown to reduce body sway.[22] Thus the sensory system has compensated for the loss of the visual reference system and adapted to use the force feedback from the fingertip to provide the body with a spatial reference. Other recent research has also demonstrated that tactile cueing yields significantly faster and more accurate performance than do comparable spatial auditory cues.[23] For instance, army study participants could effectively respond to tactor messaging while navigating a physically challenging obstacle course.[24] Likewise, the human tactile channel has been demonstrated to be an effective system for providing situational awareness (aircraft orientation) to pilots. The Tactile Situation Awareness System accepts data from various aircraft sensors and presents this information via tactile stimulators or “tactors” integrated into flight garments. This system uses a number of vibrotactile transducers (tactors) integrated in a flight vest and connected via a processor to the aircraft control panel, which gives access to the avionics data in various aircraft-specific formats. By arranging the tactors in an intuitive nature around the body (“body referenced”), flight parameters

such as attitude, altitude, and velocity, as well as navigational and threat warnings, can be provided via the sense of feel to the pilot.[25]

Vibrotactile displays are an intuitive, nonintrusive display that in the balance training system described is preferable to visual and audio cueing.[23] Compelling data from studies of aircraft pilots using tactile stimuli data displays that influence both the perceptual and response processes involved in visual-vestibular-somatosensory integration[26] continue to encourage adaptation of this technology to a medical application.

Statement of the Problem and Goals to Be Achieved

Standard care physical therapy intervention directed at reducing "fall risk factors" has been unsuccessful in significantly reducing the rate of falls. Fall risk factors are quantified by surrogate balance tests with protocols incorporating activities of daily living such as static standing with eyes open or eyes closed, bend and retrieve, forward reach, or sit-to-stand. The result of intervention is quantified by a rater's subjective opinion of patient performance and then by linking the score to the potential for falling rather than by counting the actual number of falls. Vibrotactile force platform technology, when integrated into standard care physical therapy, may be successful in objectively measuring sway[27] during functional activities, thus improving postural control. Intervention outcomes should be quantification of independence and reduction of falls in elderly populations.

The effects of similar vibrotactile devices have been investigated (please refer to Chapter 2), but these devices have not been investigated in physical therapy clinical settings. Moreover, the device investigations have been limited to upright stance: transitional movements facilitated by vibrotactile displays such as forward lean and rise found in sit-to-stand have not been investigated.

Study Purpose

The purpose of this study is to determine if the force platform vibrotactile device has clinical value in training patients in postural control of sway, balance, and mobility required for refining or relearning large movement tasks such as sit-to-stand. In addition, the study purpose is to observe how the device will integrate into a normal physical therapy clinical work flow, and acceptance of vibrotactile tactile stimulation by patients.

Study Aim

The aim of this study is 3-fold: first, to demonstrate improvement in sit-to-stand balance when training with the force platform vibrotactile device; second, to determine an efficiency relationship between the force platform vibrotactile device and standard care physical therapy; and third, to determine a relationship between the rate of falls and the subjects who have trained with the device.

Study Goal

The primary goal of this study is to determine a relationship between force platform vibrotactile displays and improvement in the sit-to-stand functional activity and reduction

of rate of falls. The secondary goal of this study is to demonstrate efficiency in physical therapy delivery of care with knowledge transfer carryover into activities of daily living, as evidenced by NeuroCom Sit-to-Stand Comprehensive Reports,[28] Dynamic Gait Index (DGI),[29] and Berg Balance Scale (BBS) observer anchor-based scores.[30] Therefore, this study might demonstrate knowledge retention as evidenced in corresponding reduction in fall rates when incorporating force platform vibrotactile technology into physical therapy standard care balance and fall intervention.

Concurrent Study Purpose

The concurrent purpose of this study is to understand the design requirements necessary for a force platform vibrotactile device that will provide adequate postural information necessary for a balance aid in a clinical setting. Although beyond the scope of this study, display accuracy and ease of usage, including intuitiveness, simultaneous accessibility to computer and patient by the physical therapists, computer program stability, product durability, and acceptance by the patient, are all critical success factors.

Relevance, Significance, and Need for Study

The relevance of research of a force platform, vibrotactile device for physical therapists is far-reaching. Not only may the technology investigated in this study be found to be beneficial in increasing the level of independence and in intervening in falls, but other like types of technology may be recognized for their rehabilitation, evaluation, and intervention potential as well. A paradigm shift may occur, resulting in the general use of

technology, specifically, dynamic feedback assistive devices for balance. In addition, theoretical frameworks within rehabilitation treatment rationales could change.

Except prosthetics for limb replacement, assistive devices for balance are usually static. For example, straight canes and walkers lend only inert reference to gravity. In general, the intent of dynamic feedback devices is to cue sensory and neural networks to provide an effective motor output response for a given task.[31] Many blind and visually impaired populations successfully use cueing technology: beeps and vibrations from global positioning systems aid in collision avoidance and navigation.[32,32]
The concept of vibrotactile cueing is to give additional or enriched information to complement postural and mobility decisions. Not all patients with imbalance may receive benefit from vibrotactile enrichment. The user must be able to cognitively apply vibrotactile information appropriately to maintain equilibrium: it is reasonable to speculate that the wearer must not be too frail or too demented in order to receive benefit.[34,35] Postural feedback can greatly increase spatial awareness and postural control necessary for mobility. The ability of the brain to reorganize and relearn functional movement activities provides an intriguing potential pathway for the retention and knowledge transfer of learned functional mobility strategies. Functional skill sets as an outcome of postural control feedback are built upon sway including static, quiet stance, and feedforward generating tilt and rate of tilt. This vibrotactile force platform guided approach to mobility could change the paradigm used to facilitate functional skills in movement disorders.

Opportunity Created by This Technology

During disequilibrium, previous movement patterns that the nervous system has come to expect are likely altered because of health issues or new task components. Therefore, understanding the task and applying manipulations to the system as a whole is advantageous to a beneficial outcome. For example, if considering only one variable, such as unequal weight distribution in sit-to-stand due to hemiplegia, applying an intervention to only the weight distribution variable disregards the other functioning components of the system.

Vibrotactile force platform guided mobility training is well suited as an augmentation of existing therapy. The device readily adapts to the physical therapy clinic work flow. Our preferred guided training system consists of a force platform and a vibrotactile belt onto which variable tactile stimuli cueing is used to facilitate postural movement, correction, or equilibrium. Each functional activity is set in advance; thus the sequence of postural movement is known. Tactile feedback is then used to enhance the patient's awareness of sway and, similar to traditional biofeedback, enhances existing sensory and neural input during each functional movement task.

Traditional Rehabilitation Theoretical Framework

Multifactorial system deficit models associate physiologic impairment with functional decline: impairments are linked to disabilities. Impairments lend themselves to intervention through rehabilitative manipulations regardless of the etiology.[11] Large movement tasks are associated with function in activities of daily living. Likewise,

attention to large movement task impairment rendered by a trained professional in a controlled environment, with a quantitative method of determining skill proficiency and progression, offers a safe, effective, and efficient approach to reducing, delaying, or reversing functional decline.

Research Questions and Hypotheses

Research Question 1

Are older adults with abnormal sit-to-stand and self-reports of fall(s) able to improve balance test scores faster and better with physical therapy standard care plus treatment with the vibrotactile force platform device than are those receiving standard care physical therapy without the device?

Research Question 2

Is there knowledge transfer between standard care treatment plus force platform vibrotactile device protocol(s), as quantified by balance test scores, including the BBS, DGI, FIM-Motor, NeuroCom Comprehensive Report, and NeuroCom normative ratio: is knowledge transfer better than standard care physical therapy without the device?

Research Question 3

Is there knowledge retention after standard care treatment plus the force platform vibrotactile device as quantified by self-reported falls: is it better than standard care physical therapy without the device?

Hypothesis 1

There is a relationship between standard care physical therapy plus vibrotactile treatment intervention and balance assessment scores, including the BBS, DGI, and FIM-Motor in a population aged 60 to 79 years with abnormal NeuroCom Sit-to-Stand Comprehensive Report scores and 2 or more self-reported falls within the past 6 months.

Hypothesis 2

There is a relationship between standard care physical therapy plus treatment with vibrotactile force platform intervention and sit-to-stand ratio scores, including NeuroCom Comprehensive Report and NeuroCom normative ratio scores.

Hypothesis 3

There is a relationship between standard care physical therapy plus treatment with vibrotactile force platform and rate of falls.

Hypothesis 4

There is a relationship between standard care physical therapy plus treatment with the vibrotactile device and NeuroCom Sit-to-Stand normative ratio scores.

Hypothesis 5

There is a relationship between standard care physical therapy with vibrotactile device treatment and standard care physical therapy only.

Definition of Terms

Balance

Balance is the ability to maintain equilibrium or to resume a position or trajectory after a disturbance**.**

Fall

ProFane (Prevention of Falls Network Europe and Outcomes Consensus Group) and other clinical trial investigators define a fall as unintentionally coming to rest on the ground, floor, or other lower level with or without injury.[36]

Disequilibrium

Disequilibrium may be caused by sensory disorders in the vestibular, visual, proprioception, and somatosensory systems and by motor control disorders in the peripheral and central nervous systems. Other defects such as loss of limb, low vision, impaired cognition, and specific nervous system disease may contribute to imbalance but is not included in this study.

A brief discussion of deficits contributing to disequilibrium follows. The *vestibular* system carries sensory information related to body equilibrium, specifically roll, pitch, and yaw motion oriented to gravity. Information is generated by the semicircular canals and maculae in the inner ear, relayed by the vestibular nerve to the brainstem vestibular nuclei, and processed by the vestibular nuclei and midbrain with corresponding muscular

contraction and relaxation known as motor output. *Vision* plays a significant role in balance: up to 20% of the nerve fibers from the eyes interact with the vestibular system. A variety of visual dysfunctions can cause disequilibrium, including head injury, vestibular dysfunction, and cerebral vascular accident (CVA.) There are 3 categories of the *somatosensory* system: (1) discriminative touch (perception of pressure, vibration, texture); (2) pain and temperature; and (3) proprioceptive sensation. Proprioception is sensory awareness of movement derived from muscular, tendon, and joint articular surfaces gathered from the peripheral nervous system and processed in the parietal lobe of the brain. These interoceptive senses provide feedback on the status of the body internally, which indicates whether the body is moving with required effort, as well as where the various parts of the body are located in relation to each other. Defects in the somatosensory system, a term often used interchangeably with proprioception, are essential abnormalities in the stimuli provided to or received by a subject's skin, joints, and/or muscles to maintain equilibrium or balance control. The *peripheral nervous system* generally relates to conductivity defects in peripheral nerves that send sensory information back to the brain and spinal cord such as a message that there is pressure on the sole of the foot or a toe is flexed. *Central nervous system* processing includes the brain primary motor cortex responsible for generating the neural impulses controlling execution of movement, the posterior parietal cortex responsible for transforming visual information into motor commands, the premotor cortex responsible for sensory guidance of movement and control of proximal and trunk muscles of the body, and the supplementary motor area responsible for planning and coordination of complex

movements such as those requiring 2 hands. Damage to any part of the central or peripheral nervous system interferes with balance.

Mobility

Mobility is the ability and willingness to move or change postural position.

Sit-to-Stand

The sit-to-stand activity is the ability of the subject to rise from a seated to a standing position. The sit-to-stand process is described in phases (Figure 1), including angle and velocity.

NeuroCom Force Platform Objective Quantification

NeuroCom components of sit-to-stand are as follows[28]:

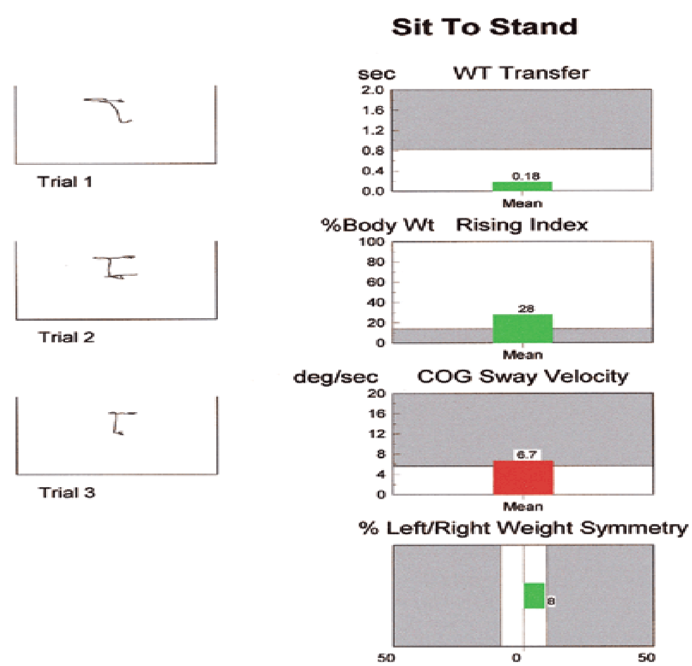


Figure 1. NeuroCom Sit-to-Stand Comprehensive Report

The COG trace uses plot stabilograms displayed on the left side of the report.

- *Weight transfer:* The voluntary shift of COG forward beginning in the seated position and ending with full weight bearing on the feet recorded in seconds.
- *Rising index:* The amount of force exerted by the legs during the after lift-off phase. Force is expressed as a percentage of the patient's body weight.
- *COG sway velocity:* The control of the COG over the base of support during the rising phase and for 5 seconds thereafter. Sway is expressed in degrees per second.
- *Left/Right symmetry:* Is the difference in the percentage of body weight borne by each leg during the active before/after lift-off or rising phase.
- *Graphic shaded area:* Gray represents performance outside of the normative data range. Green bars indicate performance within the normal range, while red bars indicate performance outside normal range. A numerical value is displayed at the top of each page.

Chapter Summary

Falls are complex and multifaceted, and equilibrium is a phenomenon whose dimensions defy simple description.[37] Prescreening of active community-dwelling adults who are over 65 years of age for fall risk factors may not predict those individuals who are likely to fall: impairment- and performance-based tests, even with health and demographic factors, did not indicate individuals who are at risk for falling.[38-40] Interventions to decrease the rate of falls are only marginally successful.

Managing postural points of instability with velocity and trajectory vibrotactile cueing to points of stability is a new approach to equilibrium. The force platform vibrotactile device exploits a COG referenced display to enrich sensory data necessary for successful balance. This paradigm for falls intervention uses spatial orientation cueing for conscious decisions regarding postural control. The study investigates the value of force platform vibrotactile technology to patients with disequilibrium as a result of multifactor physiologic system decline, as seen in older populations with abnormal sit-to-stand parameters who also report falls. The force platform vibrotactile device provides accurate, constant biofeedback data as sensory enrichment that is referenced to gravity. The device is able to provide consistent data so that when applied repetitiously, it may encourage brain plasticity adaptation. Subjects with multifactorial sensory neural deficits may find positive benefits in balance test scores and a corresponding decrease in the rate of falls. This multivariant model is in contrast to the single variant model currently guiding traditional physical therapy fall intervention programs.

Previous investigation found a positive relationship to NeuroCom Sensory Organization Test (SOT) scores when wearing an inertial accelerometer vibrotactile balance device, which suggests that further research be directed towards dynamic gait or locomotion.[41] However, advancement of vibrotactile sensory enrichment knowledge should include simulated activities of daily living, such as standing up out of a chair, and would significantly advance the body of knowledge and the efficacy of a vibrotactile cueing approach.

The growth in senior populations, rising health care costs related to injury sustained from a fall, and cost of caregiving to patients with limited independence makes finding ways to promote independence and reduce the number of falls, especially in senior populations, of paramount importance. Moreover, a positive relationship between activities of daily living, increased level of independence, and reduction in rate of falls to the force platform vibrotactile device would introduce a spatial orientation rehabilitation product to the existing equilibrium training protocols. Clearly, new intervention strategies are needed to improve mobility and balance and to decrease falls.

CHAPER 2: REVIEW OF LITERATURE

Introduction

Balance and mobility may be significantly impaired in those reporting falls.[42] As individuals age, they accumulate larger numbers of chronic conditions and disabilities, and their potential for experiencing adverse outcomes from falls increases substantially.[43] Loss of independence mobility and falls affect not only individuals, but also family members and the community that contributes to care.[44] Approximately 35% to 40% of community-dwelling older adults fall: 40% to 60% of these falls lead to injury, about 5% result in fractures, and another 5% to 10% result in other serious injury requiring medical attention.[45] One-third of seniors aged 65 years and older reported a fall within any given year, and 50% of those aged 80 years and older reported falling each year.[12,46] Falls are the most prevalent cause of injury in older persons in the United States, and rank 13th as the leading cause of death worldwide.[47] Moreover, falls are ranked 14th as the leading cause of burden of disease in older persons in high-income countries worldwide.[48] However, the actual number of falls and subsequent injuries are not known. Many people that fall believe significant injury such as fractures must be sustained before a fall is considered relevant and thus worthy of reporting.

Although falling represents a general risk, some population groups are more prone to falls, such as those with pathological conditions, which might include stroke, resulting in hemiplegia, and multiple sensory and motor dysfunctions that often affect the elderly.[43]

Primary reasons for falling include (1) change in postural position, (2) hindrance from an object or force, and (3) medical conditions resulting in dizziness, vertigo, or syncope. Extrinsic factors such as fixed obstacles that require navigation can also contribute to imbalance.[49] However, only hindrances of a magnitude that overcome sensory and neural network redundancy will result in falling.

The cost of falling affects our medical dollars. Accordingly, a steady sustained growth of elderly populations, especially in high-income countries, challenges policy makers, particularly within the health care sector, as utilization of services increases. By 2020, elderly falls will cost the United States more than $20.2 to 43.8 billion annually, increasing to 240 billion by 2040.[46]

On the basis of US Census Bureau projections, the nation's population is projected to increase from 281 to 392 million by 2050. A population aged 65 years and older is projected to be 16% of the total by 2029, and that percentage will hold steady to 2050. Life expectancy is projected to increase from 76 years in 1993 to 82.6 years in 2050.[46] Cost projections indicate that 24.5 million seniors will spend over 2 billion dollars annually, with an average of $19,500 per person, on medical treatment related to falls by 2029.[44,46] Moreover, meta-analysis finds that estimates of effectiveness of fall prevention programs for older adults are inconclusive and the strength of the evidence overstated.[2,50] Even though older adults are capable of independent walking, there could be a significant decline in their ability to control equilibrium, resulting in trips, slips, or missteps, but to date, sensory and motor tests to predict who will fall have yet to be developed.[1,51-53]

Currently, fall rates for people aged 65 years and older remain largely unchanged. Gillespie et al.[3] systematically reviewed 62 randomized clinical trials on fall interventions from 1992 to 2009. The trials were handicapped, pooled into categories, and analyzed. Investigators concluded that multifactorial intervention was minimally beneficial in reducing the incidence of falls; however, no single intervention could be identified as notably effective.[50,53] To date, exercise training is thought to be superior to education and home safety assessment and modification,[54] but the number of patients needed to be treated to prevent 1 person having a fall is estimated to be 9.8: the number of patients needed to be treated to prevent 1 person having a fracture is 45.5.[2,3]

Consequences of Imbalance

Consequences of imbalance include decreased quality of life from limited mobility or effects of injury, as well as utilization of finite health care resources. Objective qualitative balance testing performance is correlated to attitudes about falling. Poor balance test scores are associated with fears of falling, perceived quality of life, the experience of daily active hours, and daily experience navigating within the community.[55]

The most common reason for loss of independent living resulting in placement in a nursing home is falls.[56] Moreover, nursing home residents with a dual classification of those who are able to rise from a chair but who are not able to stand unaided account for 81% of falls in the nursing homes: this fall rate is the highest of all other activities of daily living including other dual classifications.[57]

Overview

The most definitive statement about human mobility is that variation is the rule. Describing human movement is difficult because biological systems are adaptive. Once the task strategies are determined and applied as feedforward, ie, sit-to-stand, stepping, reaching, and walking, the individual's nervous system selects the appropriate movement for a given situation.[19] Previous movement patterns that the nervous system has come to expect from feedback are likely altered because of health issues or new task components.

If considering only one variable, such as unequal weight distribution in sit-to-stand, applying an intervention to only that variable disregards the other functioning components of the system. The solution to independent mobility may be to accentuate sway asymmetry towards the stronger direction. Optimal direction of postural control, in turn, is directed by vibrotactile data display. Therefore, understanding the task and applying manipulations to the system as a whole is advantageous to a beneficial outcome. Static human posture resembles an inverted pendulum: center of mass lies at approximately 55% to 66% of the body height. Balance resulting from equilibrium is a state of maintaining center of mass over a base of support. Traditionally, human balance control is based on the subject's ability to control angular deviations of the center of mass within a base of support.[58] When the center of mass exceeds or moves out of the base of support, a fall is likely to occur.[59] Current theory believes that the human neural network uses angular velocity at center of mass as a constant to stabilize posture.[58] In addition, any manipulations of variable(s) need to be referenced to a constant. Gravity is the ideal

constant from which to reference human balance. This theory suggests that center of mass exceeding COG is influenced by velocity. Postural stability must not exceed limits of stability; therefore, sway velocity movement about COG must also be limited.

In general, physical therapists attempt to normalize sensory or neural balance deficits through habituation, repetitious provocation of symptoms, and compensation, engaging other sensory neural systems to augment or replace the site of lesion deficit and the musculoskeletal dysfunction with strength, flexibility, and endurance or by bracing. Difficult motor tasks are often decomposed so that control of individual body segments is practiced in isolation. The concept of bridging unstable transition points with feedback-directed sway trajectory and velocity is a novel idea for physical therapists.[19,60] Multivariant models of mobility of large movement tasks acknowledge all forces influencing mobility, but feedback reference is constant only to gravity. Providing enriched COG and velocity data to the torso by the force platform vibrotactile device may promote stronger neurologic network connections that, in turn, may result in improved mobility and a reduced rate of falls. Vibrotactile cueing from force platform data referenced to gravity may be a link to improvement in small movement static standing sway, thought to be beneficial in habituating vestibular deficits, or in large movement dynamic postural control needed for activities of daily living.

This idea has led to the development of a system of protocols that identifies individual components of a task in terms of sway, velocity, trajectory, cadence, and downward force that are cued by the force platform vibrotactile device hardware/software. This system of

hardware and software may promote strategies for task performance and skill acquisition necessary for successful human mobility.

Historical Overview of the Theory and Research Literature

The most prominent approach to mobility since the 1970s is a “cybernetic metaphor,” in which the body receives and processes sensory input that it then uses to generate motor output.[19] To effect change in mobility by standard care physical therapy, physical therapists teach exercises intended to “habituate” sensory and motor systems with hopes of repairing the system, or effect “compensation” by instructing the patient to alter the skill sets of a task. Of course, any type of human movement alters the sensory and motor fields, and intentionally altering skill sets are only best-guess applications. In reality, the task requiring mobility, repetitious stepping, for example, is initiated by the nervous system, which calculates and adjusts the relevant parameters with each application.

Physical therapists have put forth a considerable effort to intervene in falls. Therefore, many physical therapists, investigators, program directors, and administrators may be entrenched in their current methods. For instance, a current outcome goal that is measured by physical therapists is variance in fall risk factors. Supposedly, improved balance test scores decrease risk of falling. Traditional tests may discriminate between levels of performance or even between fallers and nonfallers, but none have been shown to predict future falls.[38,58,61] Moreover, a recent study has found that traditional physical therapy exercise may be more effective under dual-task conditions mirroring activities of

daily living rather than under the current one-task model.[62] In addition, and contrary to the current viewpoint of falls intervention, this study addresses task performance and counts number of falls rather than relying on intrinsic or extrinsic single fall risk factor manipulation found in current meta-analysis.[50]

Force Platform Vibrotactile Device

The force platform vibrotactile device is a method of communicating real-time sway feedback, to reference spatial orientation, from data gathered from gravity and velocity. Vibrating tactile stimuli give enriched information to complement postural and mobility decisions.

Historically, posture has been defined through reflex terminology and facilitated through controlled sensory feedback.[63] The subject receives sensory input (feedback) from having completed the task previously and makes the necessary postural adjustments to complete the task in the most effective, efficient way. For example, if the base of support is exceeded, resulting in imbalance on the first try, adjustments to the base of support and/or muscle activation will be made on the next try.

Feedback in steady stance refers to quieting movement, with tactors vibrating only when preset angular parameters are exceeded. Feedback in static stance with eyes closed, for example, is particularly helpful when habituating vestibular hypofunction.[64]

Feedforward also occurs as a result of learning through experience: feedforward is learned through trial-and-error practice and must be subject generated and goal or task oriented. Postural control through motor output finds muscle activation around joints in anticipation of the task. Positive feedforward stimulus refers to the tactors vibrating when an angle or target is reached. Motor learning occurs when the subject is actively involved in the task and advances from using only the feedback responses to using feedforward control. Extending the limits of stability improves balance and reduces falls, especially in the elderly.[65] Both techniques are sensitive to sensory disturbances that determine sway amplitude and sway paths, which correlate to spatiotemporal information that directs postural control.[66,67]

The vibrotactile force platform guided mobility device uses preset parameters for cadence, velocity, trajectory, and time on target to achieve repetitious mobility. As realized from previous limited clinical application, force platform vibrotactile devices are useful for guiding large movement tasks, such as exploiting feedforward limits of stability or promoting quiet stance feedback on a rocker board, in subjects with disequilibrium.

The force platform, accompanying software, and vibrating tactor transducers display real-time movement of the patient. Compartmentalized software in the device accommodates 360 degrees of motion: the display is organized on 360 degrees of motion divided into 8 quadrants. Each quadrant corresponds to 1 to 8 tactors, with tactor 1 at the subject’s navel, tactor 6 at the spine, tactor 3 slightly posterior/superior to the right anterior iliac

spine, tactor 7 slightly posterior/superior to the left anterior iliac spine, and tactors 2, 4, 6, and 8 midway between each. Pressure from the subject's feet is captured from the force platform and displayed as a "snaking line" on the computer monitor. Usually the operator or physical therapist is observing the monitor to adjust limit-of-stability parameters or to identify force pressure placement. The computer is able to record data from the subject's movement. When limit-of-stability parameters are exceeded, the tactors vibrate.

Changeable characteristics of each compartment guide the wearer via vibrotactile stimulation to a specific target. Each programmable compartment provides meaningful information via vibration on the torso to guide mobility to achieve a task by changing the vibratory characteristics of each compartment derived from force platform COP and displayed as velocity, trajectory, and cadence. This device uses an array of 8 vibrating transducers known as tactors that are specifically designed to enrich vestibular and somatosensory display information. Displays include steady stance by presenting nonvibration, avoid or move away from the vibration, and tactor-quiet cueing until preset angular parameters are exceeded. For example, weight shifting to limits of stability uses positive tactor-on vibration cueing navigation towards the target, and when an angle or target is reached, postural sway is stabilized by tactor quiet.

<u>Application of the Force Platform Vibrotactile Device</u>

Protocol applications use sway trajectory to notify the wearer of abnormal limits of stability quickly enough for cognitive postural adjustment. Midline is achieved by quieting the vibrating tractors: increased postural sway exceeding the preset limits of

stability activates the tactors. Variable tactor on/off vibration directs postural positioning to a target. In addition, tactor placement gives trajectory information so that the wearer can purposely control the direction and magnitude of postural sway. This study places the tactors around the torso; however, it is feasible to place tactors to circumvent any center of mass, such as the head in Goebel's[68] study or around the calfs in Oddsson's[69] application.

Data displays must be intuitive. For example, a person might be more likely to turn towards a tap on the shoulder. Likewise, multiple resource theory is a theory of multiple task performance that has practical application for vibrotactile data recognition. The importance of multiple resource concepts is its ability to predict dual-task interference levels between concurrently performed tasks.[70] This means that vibrotactile stimulation must be consistent with the underlying neurophysiologic mechanism of the performance of the tasks.

Pacinian Receptors

Vibratory stimulation activates superficial tactile receptors under the dermis. Tactile receptors are the most rudimentary of spinal cord and brain neurologic vestiges, developing early on in the fetus and retaining stimulation properties even with neural network deficits. Phasic mechanoreceptors, especially pacinian receptors, are useful in sensing vibration. When the skin is distorted with intermittent rapid pressure, but not with continuous pressure, action potentials are formed. Phasic receptors return quickly to pre-

action-potential status; thus, the sensation of vibration does not accommodate over time, even with increased pressure, and is sensitive to rates up to 400 Hz.[71,72]

Description of Force Platform Vibrotactile Hardware

This device incorporates advanced electronics developed within the past 9 years that are low-cost, high-performance sensors, tactors, processors, and controllers. Currently, the physical therapist places the apparatus onto the wearer and runs the software interface. Future devices are anticipated to be smaller and lighter in weight, not to require the wearer to need help with body placement, and to become increasingly user friendly.

The *force platform* (Figure 5) is a standard pressure-sensitive dais. Four pressure sensors, one in each corner, calculate sum of pressure, and quantify COG-to-sway data. The force platform is large enough to accommodate stepping, lunging, and pivot turns, as well as accessories that simulate chairs and steps. Maximal weight accommodation is 180 kg.

Postural control is achieved by varying pressure against the base of support. Only when weight is distributed equally, for example, between each foot when standing upright, can center of pressure also be described as COG. Similarly, large movement dynamic tasks such as sit-to-stand are referenced to postural base of support, which is the buttock when sitting, and then to center-of-foot pressure when standing. The force platform vibrotactile device (Figure 2) utilizes COP data gathered from a force platform that activates vibrating tactors worn about the torso to direct postural movement. Continuous vibrotactile COP data are received throughout the task.

Tactors, usually vibrating at 250 Hz, are spaced around the torso and provide sway information by changing the location of vibration. Five pulses per second is the highest vibration rate having individually perceivable pulses.[73] Tactor rate and gain can be adjusted. In this study, tactor rate and gain remain constant.

The central computer processor, or *controller*, used in the current balance device research is small, 9 cm by 9.5 cm, and weighs about 1.4 kg. The sensor signals are digitized in real time, typically at over 100 samples per second. The central processor generates data displays. It is estimated that spatial orientation feedback information must be within 0.1 to 1 degrees to be useful.[16]

The tactor and controller apparatus is fixed to the *tactor-belt* garment and worn on the posterior low back. The belt is adjustable to waist size, and the tactors shift accordingly to represent anterior, posterior, lateral, and diagonal movement patterns.

Figure 2. Patient Wearing Device

Description of Force Platform Vibrotactile Device Software

Software accommodates 360 degrees of motion by dividing the circle into 8 modules much like slices of a pie. Configurable characteristics of each module (Figure 3) guide the wearer via vibrotactile stimulation to a specific target.

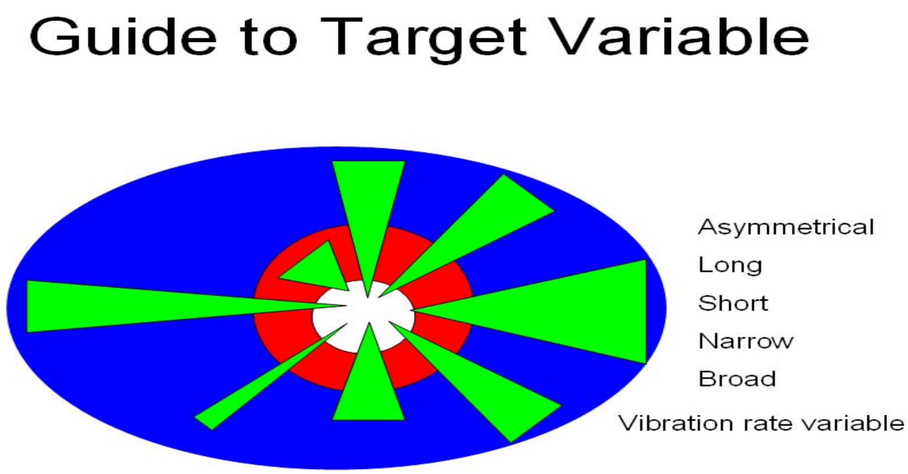


Figure 3. Variable Conditions Guide to Target

Application of Force Platform Vibrotactile Cueing

Vibrotactile feedback/feedforward cueing gives additional information to complement postural mobility decisions. Parameters for cadence, velocity, trajectory, and time on target may be used to achieve repetitious mobility. As realized from previous limited clinical application, force platform vibrotactile cueing is useful for guiding large movement tasks, such as extending the sway limits of stability in the elderly who fall or promoting quiet stance on a rocker board in subjects with sensory hypofunction.

There are distinct differences between various styles and strategies used from person to person in sit-to-stand. For example, some subjects may dip their head, while others may swing their arms forward. Therefore, the goal of the force platform vibrotactile device is to enable successful movement strategies rather than compute specific forces and angles.

The task of sit-to-stand (Figures 4-6) is described in 4 phases: (1) sit, (2) before lift-off, (3) after lift-off, and (4) stand. Sit is a steady state that is measured by COP and sway; before lift-off is characterized by acceleration of momentum, and trajectory is measured by direction; after lift-off finds downward pressure through the feet and is measured by force; and stand finds momentum decelerating and is again measured by COP sway. Subjects present their own task timing and strategies. It is anticipated that wobble at any phase will strongly affect the success of the task.

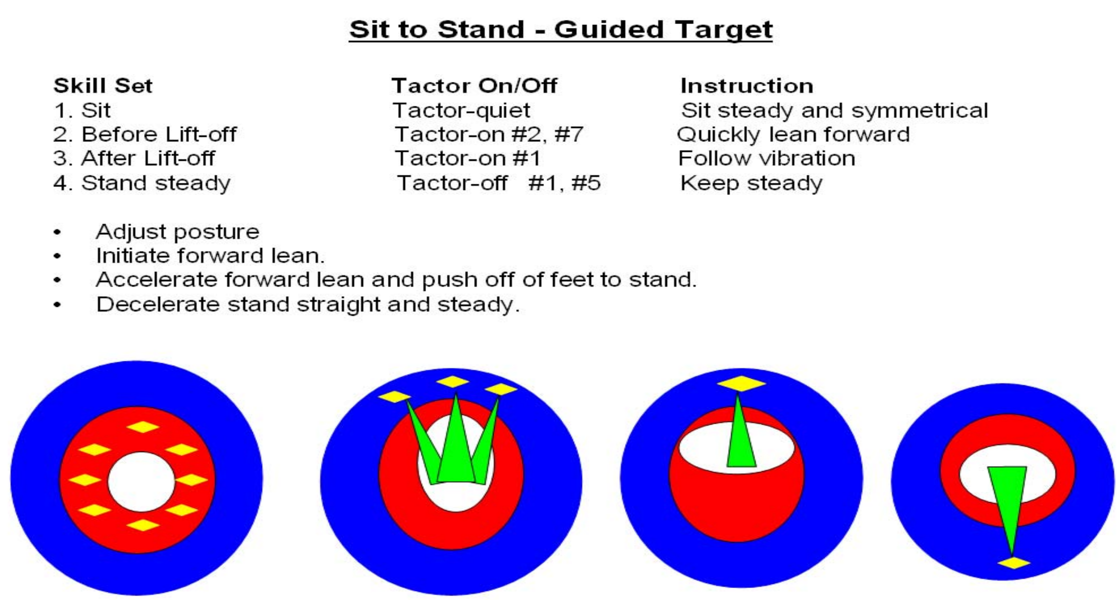


Figure 4. Sit-to-Stand Guided Targets

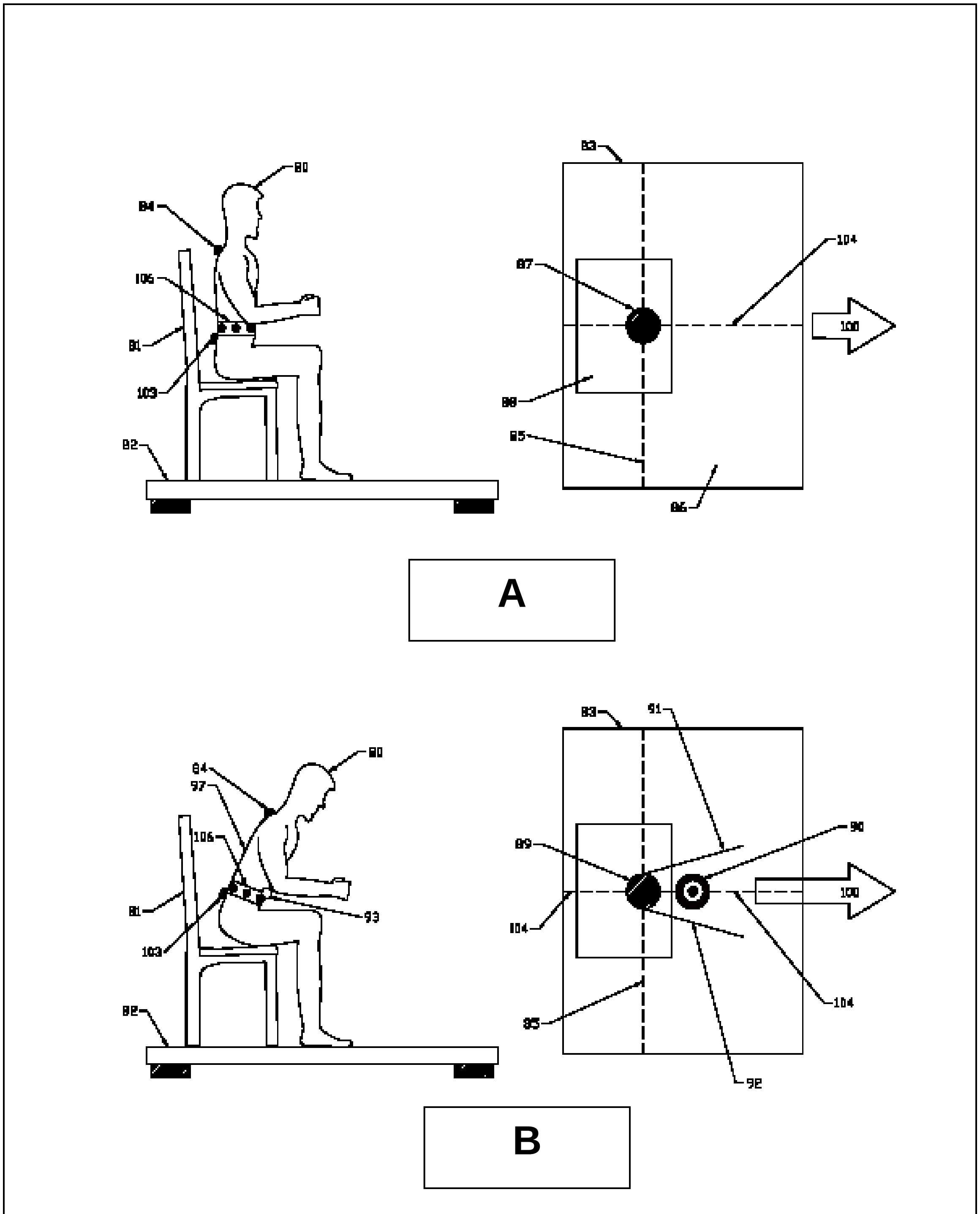


Figure 5. Force Platform Vibrotactile Device. A. Sit. B. Before Lift-Off.

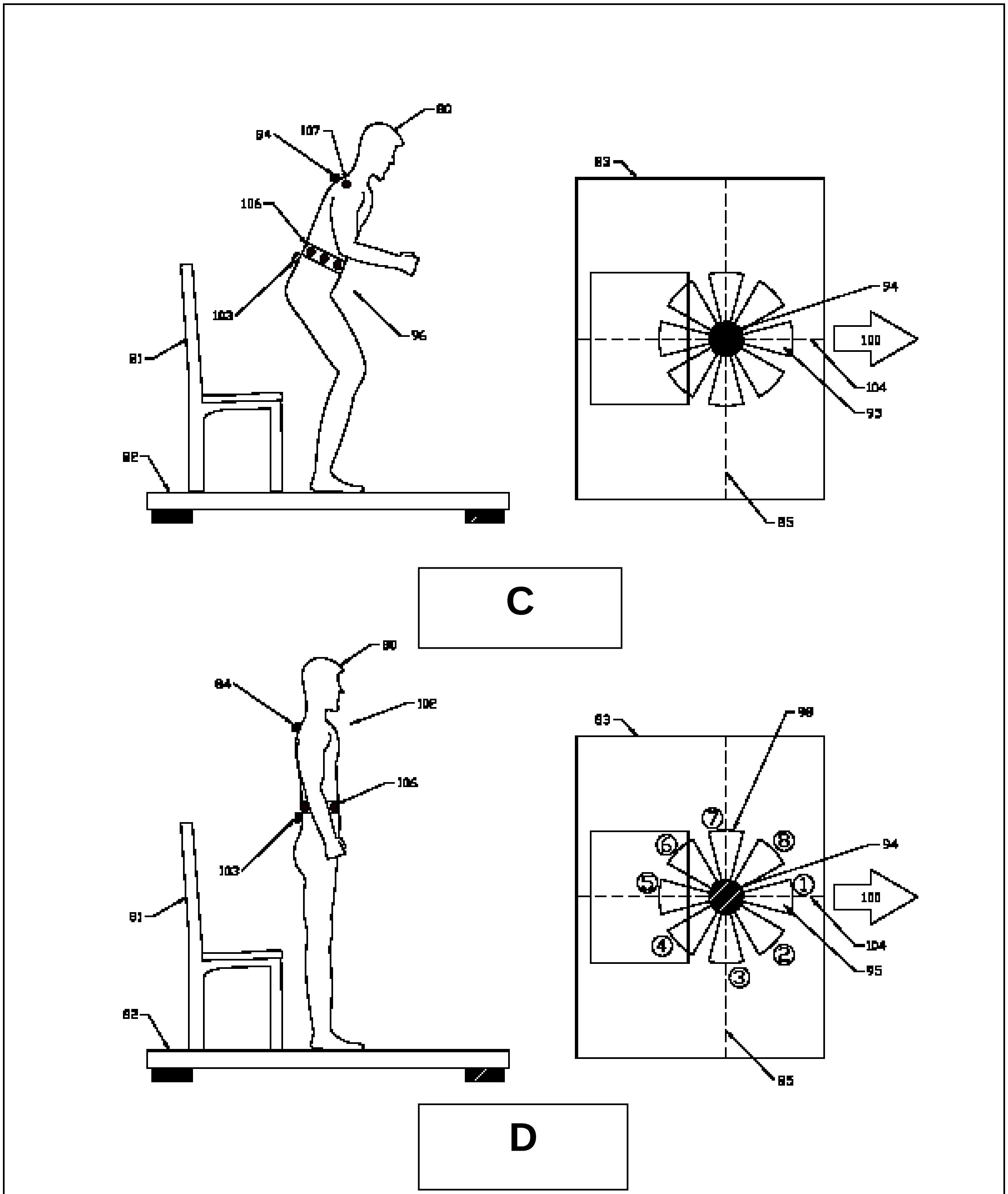


Figure 6. Force Platform Vibrotactile Device. C. After Lift-Off. D. Stand.

Significant Finds and Application of Related Technology

Previous Research

Rupert initially developed the vibrotactile concept for navy divers as an underwater communication aid in the late 1970s. Wall, through the NASA space program, developed an inertia device for astronauts. Much of their original technology has been adapted for medical application.

Previous investigations of inertia sensors to provide vibrotactile reference to upright stance have proven to be beneficial in laboratory study subjects as an aid to postural control.[14,15,73,74] In addition, a positive relationship was found to NeuroCom Sensory Organization Test (SOT) scores when subjects wore an inertia balance prosthesis.[41]

An inertia vibrotactile prosthesis or device, using accelerometers rather than force platform sensors, has been shown to improve upright static stance and limits of stability weight shifting,[14] as well as DGI[15] and Functional Gait Analysis scores.[41] Wall and Wrisley[75] used inertia sensors to collect data referenced to gravity. Postural tilt and rate of tilt was delivered to the subjects via inertia sensors and vibrotactile cueing while completing the DGI. Wall[76] has also indicated positive benefit to older individuals when performing the DGI protocol.

The tactor method in general has been validated on patients with vestibular loss as compared with normals. In Wall's[18] study, the finds were more evident in subjects with

severe deficits than in those with moderate deficits. In addition, the tactor method was validated on patients with vestibular loss as compared with normals.[77] Wall[74] also concluded that the method could be applied to balance prostheses that use other (force platform) technology.

Oddsson[69] used foot pressure sensors in a shoe insole to construct COP data that was displayed via vibrotactile stimulation to the lower legs. Immediate beneficial effects in DGI scores were found. Oddsson concluded that 72 treatments of tai chi or over 60 treatments of standard care physical therapy were required to reach the same outcome. Oddsson's[69] device, named The SmartSock, maps the ground reaction force experienced by various areas of the foot during gait, and data are displayed via an array of tactile transmitters mounted round the calf of the wearer.

The inertia device used by Allum,[78,79] SwayStar, gathers sway data, and through tactile and auditory stimuli, relays tilt and rate of tilt. Proof of concept was shown to be successful in vestibulopathic subjects while they were standing. Allum's[18] studies also find that the benefit was more evident in subjects with severe deficits than in those with moderate deficits.

The device used by Goebel[68] investigated a head-mounted accelerometer-vibrotactile display that was attached to a baseball-style cap. He found significant benefit to bilateral vestibular hypofunction subjects undergoing NeuroCom SOT conditions 5 and 6.

Sienko completed a doctoral dissertation investigating the relationship between an accelerometer sway reference vibrotactile device to NeuroCom SOT and gait performance. Sienko's[77] NASA and NIH-funded dissertation found that multidirectional vibrotactile tilt feedback reduced postural sway during multidirectional support surface perturbations, which had both short- and long-term effects on increasing postural stability. Sienko also recommended investigation of vibrotactile devices to control sit-to-stand posture.

Dozza has recently completed a doctoral dissertation investigating auditory, visual, and vibrotactile sensory enrichment to improve postural control. A crossover design was used comprising 9 unilateral vestibular loss subjects who wore a trunk tilt gyroscope (accelerometer)-type biofeedback device during tandem gait. Subjects with unilateral vestibular hypofunction used vibrotactile feedback as a tandem stand and tandem gait training aid. This study concluded that vibrotactile biofeedback effectively improved stability and performance accuracy; however, practice over time without feedback also found improved dynamic motor performance. The investigators concluded that tactile feedback outcomes were similar to practicing the tandem gait task without the device.[80]

When forced stepping was initiated via treadmill activation, Asseman[81,82] reported that younger normal subjects and younger subjects with balance disorders found mixed benefit: older normal subjects with slow reactions found no benefit.[81,82] Subsequent study by this same group of investigators also evaluated subjects with balance disorders:

vibrotactile cueing produced shorter stepping times and significantly shorter protective stepping time in elderly subjects.[82]

Similar BrainPort[64] technology with electrical stimulation via inertia balance prosthesis has been found useful in measuring linear and angular tilt and acceleration and in reducing lateral postural sway when used as a limit-of-stability feedback enrichment aid. The device delivers sway data via electrical display patterns on the tongue.

Allum,[79] the patent holder of prosthetic sway feedback, and Horak[83] are concurrently investigating auditory prosthetic feedback with the intent of controlling trunk sway associated with reduced sensory input with auditory signals of data gathered from inertia sensors. Nintendo Wii Fit is a force platform device used by some physical therapists. This device relays postural control data via visual and auditory display. The problem with this approach is that vision and hearing are slower primary senses, and these senses are hardwired to perform other more familiar tasks. Vibrotactile display could advantageously free visual and auditory sensory channels by conveying information about postural control through touch.[14,64]

<u>Kinesthetic Learning Constructs</u>

Kinesthetic learning is a style in which learning takes place by the subject when carrying out a physical activity. Tactile learning is promoted through touch that includes vibration. Physical therapists often rely on guiding limbs by using techniques such as rhythmic

initiation and repetitious developmental sequencing to teach skills. Similarly, proficiency in sport activities is often learned by repetitive practice.

The force platform vibrotactile device used in this study kinesthetically teaches skills by guiding trunk and limb movement, with tactor-on, tactor-off vibration cueing; continuous positive tactor-on cueing to maintain the target; and negative variable and/or tactor-quiet cueing when the target has been lost or exceeded. By conveying real-time continuous movement data generated from the force platform and transferred to the subject via Bluetooth vibrating tactor(s) stimulation, the subject is able to control his/her momentum and trajectory with postural changes.

Neural Plasticity Implications

Neural plasticity is believed to be the basis for learning in the maturing brain and physical rehabilitation relearning in the damaged brain. Experience-dependent neural plasticity occurs through physical rehabilitation in an enriched environment that is consistent, immediate, and relevant. The qualities and constraints of experience-dependent neural plasticity may be of major significance to rehabilitation efforts for individuals with motor control disorders.[84] A plethora of studies confirms the notion that learning new skills, enrichment of previously acquired skills, and damage of the nervous system can cause functional and structural reorganization of the brain.[85,86] Recognized as an intrinsic property of the human central nervous system is neural plasticity: structural and functional brain reorganization occurring past the developmental maturation period.[87] Brain reorganization can be maladaptive plasticity, which is defined as behavioral loss or even development of disease symptoms resulting from plasticity changes.[84] For example,

peripheral sensory differentiation on amputations by subcutaneous lidocain injection triggers a system-wide reorganization, with spatiotemporal cortical plasticity paralleled by subcortical reorganization.[88] Furthermore, an enriched environment can promote brain plasticity in animal models of neurodegenerative diseases such as Huntington's and Parkinson's, as well as of brain injury.[87]

The challenge is to understand cellular mechanisms underlying training-induced neuroanatomic plasticity and correlate behavior consequences in order to adapt treatment strategies for patients with brain injury or neurodegenerative disorders.[87] The notion of improving level of function through neuroplasticity opens possibilities that sensory enrichment may be beneficial to patients with neural diseases such as Huntington's or Parkinson's disease. In addition, patients with head trauma such as TBI may benefit from the consistent and relevant repetitive cueing delivered from the vibrotactile device.

Theoretical Framework of Balance and Postural Control

When referring to human balance, postural control is a result of relevant parameters in the nervous system obtaining equilibrium. Similar to an aircraft reference to the horizon, equilibrium in human balance on Earth is always referenced to gravity.[89] Spatial orientation and equilibrium point control in human movement is a hypothesis conceived as a means whereby the central nervous system is able to control movement by a relatively simple shift in equilibrium position: there is no explicit need to compensate for task dynamics.[59]

Motor learning is the formation of an internal encoding of muscle activation patterns that compensate for the effects of predictable environmental forces as dynamic task skills are acquired.[59] To maintain balance, a biphasic, ballistic-like pattern of torque, which can control both position and sway amplitude, is repeatedly used to control equilibrium and is essential for task performance.[90] Control of sway size is caused by improvement in the accuracy of the anticipation of torque impulses.[90] Specifically, sway size is velocity and trajectory. Therefore, controlling acceleration/deceleration and positioning will enhance equilibrium.

Referencing balance and postural control to gravity is a feedback model that allows for variables in both the individual and in mobility tasks. Accuracy needed to accomplish a large, goal-oriented movement such as sit-to-stand is achieved by manipulations of systems globally because of nervous system redundancy. Redundancy is so that broad, linear, aberrant individual variations, such as vestibular hypofunction or nerve conduction deficits, can be mitigated. Because of the feedforward nature of mobility tasks, especially large movements such as sit-to-stand or ambulation, small variations in COG, momentum, and trajectory may lead to widely divergent results.[19] The goal, then, is to encourage successful movement strategies by referencing postural control to gravity rather than normalizing, for example, lower extremity joint angles, leg length discrepancies, or asymmetrical muscle strength.

Sensory and motor systems are interdependent and redundant, using information from multiple sources with fluctuation of quantity and quality as the neural system selects

parameters. For example, the cutaneous, proprioceptive sensory system feels pressure under the feet; joint and muscle spindles are sensitive to joint position and kinetic movement; and cognition or brain processing estimates the motor response magnitude. The body relies on the interaction of a multitude of systems to control balance and posture. As illustration, the vestibular system in the ears orient upright stance, especially when the eyes are closed and the surface is compliant, but the somatosensory system is primary when the surface is solid. By disrupting the somatosensory and visual input, a test procedure for analyzing a subject's balance control, one is able to focus more particularly on the vestibular balance control mechanism.[16,91]

Balance disorders, especially in the elderly, are predominantly multicausal, with imbalance occurring because of deficits in more than one sensory and/or motor pathway.[92] Accordingly, hindrance by objects or forces, including tripping and slipping, becomes significant when balance deficits limit the patient's ability to overcome the obstacle.

In the same way, balance is not an isolated activity but rather, a flexible and varying integral part of all movement; balance underlies our capacity to perform a wide range of tasks that make up normal daily activities.[61,93] Complex activity involving cognitive, biomechanical, sensory, motor control, and central integrating mechanisms work interactively in creating task-specific balance. Therefore, the process of balance must be considered in total and not by isolated individual mechanisms.[92] Moreover, balance requires control of gravitational forces to maintain posture and acceleration/deceleration

of forces to maintain equilibrium. The neural network plays a crucial role in producing skilled, coordinated movement as it processes information from the biological nervous system to all other associated sensory and motor entities and as it isolates joint biomechanics against these forces.[94,95]

In addition, balance is strongly correlated to the level of functional mobility, ie, gait weaving, turning around, reach up, stand up, and bending forward. Functional mobility assessment is a valid means to evaluate the ability of older adults to integrate dynamic balance control into the performance of daily activities, including sit-to-stand.[3,96,97] For instance, sit-to-stand is also correlated to the likelihood of falling.[30]

Brain Plasticity

Two primary goals of physical rehabilitation are to (1) prevent degradation of neural circuits not actively engaged in task performance for an extended period, and (2) support functional recovery through enriched training by shifting novel function to residual brain areas.[84] Thus, the improvements in sensory and motor performance brought about by enriched rehabilitation are accompanied by profound plasticity.

Earlier studies confirmed the relevance of cortical plasticity following vibrotactile sensory enrichment, but they did not determine the crucial stimulus parameters that led to the observed brain reorganization.[98] More recent studies demonstrate that time, amplitude, and duration of vibrotactile stimulation are constraints of flutter stimulus

leading to proportional increases of sensory absorption and consequential brain plasticity in animal models.[99,100]

Learning in a neuronal network with sensory input to motor output is not induced by individual stimuli. In fact, synapse saturation during the learning process finds excitation balanced by inhibition: eventually similar patterns generate a threshold response, and neurons that cannot provide information are silenced.[101] The brain has a built-in mechanism that allows change according to experience.[102] For instance, sensory stimulation can affect cortical maps, especially when enriched environments combine with increased sensory stimulation for learning new activities. Accordingly, the brain is dynamic and must be trained and stimulated to gain new skills or relearn previous skills with attendant increases in synapses.[103] Repeated movements reinforce neural connectional patterns, but those patterns weaken if the movements have not been recently executed. This principle underlies the beneficial effect of practice.[104] Repetitive training should be delivered during sustained functionally related movement. Enrichment information should be intuitive and relevant in order to gain results.[105,106] This guided approach to mobility could change the paradigm that physical therapists use to teach functional skills.

Force platform vibrotactile stimulation is a concept that merges clinical human feedforward/feedback performance theory with sensory enrichment theory for learning and/or relearning mobility skills. To generate effective motor patterns for locomotion and extremity manipulation that are task specific, postural positions and joint movements

must be repetitious and meaningful.[107-109] Multivariate models of mobility of large movement tasks acknowledge all forces influencing equilibrium, but reference is constant only to gravity and velocity. Providing enriched COP or COG and velocity data via force platform vibrotactile devices may promote stronger neurologic network connections that, in turn, may result in a reduced rate of falls. Mal adaptation of postural control and gait abnormalities are suspected to occur when focus is on achieving the task rather than the skill set(s) of the task such as sway. Fall rates may be evidence of brain plasticity theory explained as knowledge retention and knowledge transfer.[60,109]

Knowledge Retention

There is little reference to knowledge retention or rate of decay following physical therapy intervention for older adults with imbalance. One could argue that a reduction in physical performance can be explained by a decrease in medical status. A pilot study investigating the effects of training elderly fallers and nonfallers noted improvement in static balance and walking patterns from training that declined after 3 months of nontraining.[109] Functional magnetic resonance imaging, positron emission tomography, and transcranial magnetic stimulation are used to measure brain cortex function, consequently documenting clinical findings. Repetitive practice can result in changes in the human motor cortex within 30 minutes that may persist for 8 to 12 weeks after training. Changes decline over time if not reinforced.[104-106] The inclusion of knowledge retention and rate of decay investigation is important for determining the rate of intervention to optimize mobility and task function.

Knowledge Transfer

Following the rate of falls will be useful to determine if the force platform vibrotactile device affects daily living activities. Conversely, reviewers of the *Cochrane Database of Systematic Reviews*[3] of literature concluded that force platform feedback of visual or auditory form for individuals after stroke did not improve clinical measures of balance, as indicated by the BBS or Timed Up and Go.[110]

Summary of What Is Known and Unknown

Dynamic balance includes the movements and forces involved in mobility. The aim of this study is to influence mobility in the large movement task of sit-to-stand by using vibrotactile display to enrich unstable points of balance with transitions between structurally stable regions. In this study, quiet sitting and quiet stance are considered stable regions, and initiations of momentum and trajectory to completion of movement are considered transitions.[19] Technology that provides real-time guidance to momentum, trajectory, and cadence is now available that may be helpful in enhancing mobility in populations with imbalance and, as a result, may also reduce falls.[73,89] The force platform vibrotactile device is a dynamic prosthesis that utilizes preprogrammed and individually designed protocols via displays of vibrotactile stimulation to acquire or improve physical performance. Computer hardware, controllers, tactor transducers, infrastructure software, and intervention protocols are designed to assess postural sway, guide movement, and train subjects with movement and balance disorders in skills intended to promote mobility, increase independence, and mitigate falls. Sit-to-stand is an important transitional movement necessary for functional mobility, including ambulation.

Moreover, balance skills such as control of sway, symmetry, postural acceleration, and deceleration are skills required in successful activities of daily living.

The aim of this study is 3-fold: first, to promote successful sit-to-stand when using the force platform vibrotactile device; second, to determine an efficiency relationship between the force platform vibrotactile device and standard care physical therapy; and third, to determine the feasibility of investigating the rate of falls in patients who have trained with the device.

The Contribution This Study Might Make to Physical Therapy

Promising results from this study could lead to a paradigm shift in the way that physical therapy interventions are provided to patients with disequilibrium, imbalance, and falls. Large movement tasks might be recognized as a series of skill sets linked through parameters of sway control. Both treatment rationale and delivery could be affected. Theoretical frameworks for evidenced-based treatment protocols could change. Emerging knowledge of the importance of consistent, functional, repetitive movement to acquire or refine tasks has been an anecdotal theme in rehabilitation. Now central nervous system imaging is able to confirm this theory. Likewise, therapeutic exercise and human performance skill acquisition may be influenced by sensory-enriched, meaningful-task techniques directed by the somatosensory cortex.

Chapter Summary

Using inertial (accelerometer) devices, several other investigators have found promising results when applying vibrotactile or auditory cueing technology to upright stance, narrow base walking, and measures of balance.[111] Balance scores improved while using vibrotactile devices. Learning models indicate that a multivariant approach to relearning of large movement functional skills facilitated by vibrotactile force platform protocols appears to be a promising treatment strategy for physical therapists.

Human postural control utilizes redundant sensory and neural controls, resulting in movement variability. Gravity is the only constant to reference angular velocity at center of mass to stabilize posture. Traditional single-variant models to describe movement are unable to account for variability, while multivariant models acknowledge all forces influencing equilibrium.

Brain plasticity is believed to be the basis for learning in the maturing brain and relearning in the damaged brain. Information must be relevant and repetitious. Repetition must be consistent, intuitive, and applied within a meaningful context. However, the user must be cognitive and reasonably fit.

The vibrotactile force platform device provides constant feedback via reference to gravity COP data displayed by vibration. Components of feedforward, large movement tasks, are referenced as multivariant models to gravity and velocity. Postural control of large

movement tasks needs mastery of feedforward/feedback of small movement tasks. Traditional physical therapy does not manage the transfer between feedback, small movement tasks, to feedforward, large movement tasks, effectively. Improving postural feedback of small movement tasks as a basis for improvement in feedforward large movement tasks is a paradigm shift in physical therapy delivery of care.

CHAPTER 3: METHODOLOGY

Introduction

The aim of this study was to quantify vibrotactile technology in a physical therapy clinical setting with actual patients. Prospective study subjects must have had the potential to benefit from physical therapy intervention. Eligibility criteria for participants and settings are described. There was no intent to control differences between therapists and locations: the generalized prescription from the referring physician as used in this study is typical of physical therapy standard care.

Instruments are typical physical treatment outcome measurements, except for the more in-depth NeuroCom normative ratio scores. For example, a physical therapist would likely report functional status in terms or level of ability as quantified by the BBS, DGI, and FIM-Motor rather than weight transfer, rising index, COG sway, and symmetry NeuroCom Activity Force Platform Sit-to-Stand.

Description of implementation, including informed consent, Health Insurance Portability and Accountability Act (HIPPA), and FDA governance of the use of a noninvasive device is presented in the Internal Review Board (IRB) submission.[Appendix A]

Overview

New paradigms in rehabilitation give rise to questions of who, what, how, and to what extent the patient will benefit. Patients who are unable to sit independently and have significant physical dysfunction are not likely to fall because of their limited ability to initiate changes in posture. Likewise, subjects who are active without history of falls or corresponding physiologic deficits are also not likely candidates for intervention. A subset population of subjects who are mobile but unsteady, especially with unsteadiness resulting in falls, has suitable candidates for force platform vibrotactile intervention. As this is the first investigation of the force platform vibrotactile device on a clinical patient population, proof of concept is also an objective.

Always present in human movement is variability. Some variables may compete with each other such that stabilizing one of them may lead to destabilization of another. For example, an increase in sitting or standing asymmetry may result in increased sway, thus contributing to imbalance as described in pusher syndrome.[112] Elemental variables such as posture or steady stance, for example, may need to be kept relatively unchanged to achieve a task.[113] Combining overall change with like-measure tools, ie, BBS, Dynamic Gait Index, and FIM-Motor, emphasized fundamental skills for postural control such as decrease in sway inherent in each of these activities. Therefore, data analysis contains the activity separately, between and within groups, and case summaries of individuals' change over time.

Study Design and Protocol

The object of this study was to determine the usefulness of vibrotactile force platform technology in a clinical setting on a patient population. It was expected that this knowledge would lead to insights that would guide device hardware and software design. The approach was to quantify outcomes of traditional physical therapy clinical measurement tools from the effect of the device.

The device employs both feedforward and feedback protocols to normalized sit-to-stand to steady stance, as determined by NeuroCom's sit-to-stand reference ranges.[68] In this investigation, feedforward is channeled sway that is initiated by the subject as specific movement to the target, and feedback means that the device limits sway. Other clinical trials to improve performance of the device, and recommend usage, have helped to define end-product intent and have been promising in a research setting. Still, the force platform vibrotactile device, including protocols, must be implemented with initial best-guess parameters, including (1) parameters for cadence, timing, trajectory, and time on target; (2) frequency and duration to achieve repetitious mobility; and (3) best-practice parameters for skill sets needed to facilitate postural equilibrium, as indicated to the participant via vibration stimulation.

<u>Clinical Setting</u>

Florida Ear & Balance Center, P.A., was formed in 1996 with the objective of providing comprehensive medical care associated with disease of the inner ear. Florida Ear &

Balance Center, P.A., is a 6,000 sq. ft office located in Celebration, Florida, and has 14 employees, including a physician specializing in neurotology, 4 audiologists, 2 physical therapists, 1 office manager, 2 nurses, 1 billing specialist, and 3 patient coordinators. The practice has seen 27,000 patients since its opening in 1996. Patients with complaints of disequilibrium are typically referred to physical therapy by physician prescription.

The physical therapy setting at Florida Ear & Balance Center, P.A. consisted of a typical treatment room and a private room for data collection. Off-site settings used in this study included hospital-based outpatient rehabilitation facilities, private practice physical therapy offices, and the patient's home serviced by home health care physical therapists.

The principal investigator/physical therapist provided standard care physical intervention to on-site control and device subjects. To control data collection bias, another physical therapist was the pre- and posttester, as well as the falls data collector for all subjects. Data result was withheld from the treating physical therapists: data collector physical therapist was blinded to the subject’s group assignment.

Research Methods Employed

Design

A prospective, pretest/posttest repeated measure design evaluated subjects' response to force platform vibrotactile intervention. The study is a randomized clinical trial case/control repeated measure design that compared results of 30 subjects in 3 groups: (1)

on-site control, (2) device, and (3) off-site control. The device intervention was used only on-site. This study compared the effect of standard care physical therapy plus treatment with the device, to standard care physical therapy only. All subjects presented with abnormal NeuroCom Sit-to-Stand activity force platform scores and self-reported 2 or more falls within the past 6 months. Change over time is quantified between groups and within subjects.

Participants

Recruitment

Letters were sent to physical therapists and selected physicians throughout central Florida; study information was displayed in the Florida Ear & Balance Center, P. A. patient waiting room; and patients seen previously by James S. Atkins Jr, MD, were spoken to with the purpose of recruiting prospective study subjects. Potential candidates aged 60 to 79 years who presented with (1) imbalance, with or without dizziness; (2) abnormal NeuroCom Sit-to-Stand activity force platform scores; and (3) 2 or more falls with or without injury within the past 6 months were invited by James S. Atkins Jr, MD, Study Medical Director, to participate in the study. In addition, James S. Atkins Jr, MD, verbally informed appropriate new and return patients about the study. Interested participants recruited specifically for the study were asked to schedule an appointment at the Florida Ear & Balance Center, P. A. with Dr James S. Atkins Jr, MD: prospective participants received an initial consultation, including physician services and NeuroCom Sit-to-Stand activity force platform testing, at no charge to determine study candidacy.

Subjects who scored abnormal NeuroCom Sit-to-Stand activity force plate normative Sit-to-Stand protocol reference ranges and who self-reported 2 or more falls with or without injury within the past 6 months were included. An even/odd last primary phone number was used to randomly assign subjects, with an even number as intervention and an odd number as control, to either the on-site control or the device group. Subjects requesting physical therapy services near their homes were included in the off-site control group.

Duration

Enrollment was open for 1 year or 64 subjects, whichever came first. Subjects received 6 physical therapy sessions 2 times per week for 3 weeks. Three follow-up sessions postintervention at 30 days, 90 days, and 180 days resulted in the study of subjects for a total of 7 months.

Subjects

Thirty-two subjects signed informed consents to participate; however, 2 subjects did not complete the physical therapy intervention sessions. Thirty subjects were subsequently included in data analysis.

Exclusion Criteria

Exclusions for all subjects included having (1) less than 20/60 corrected vision; (2) artificial limbs; (3) an inability to sit unaided for 2 minutes; (4) an inability to stand with a cane or unaided for 2 minutes; (5) an abnormal Mini Mental State Examination (MMSE); (6) diagnoses of sarcopenia, Alzheimer’s, myasthenia gravis, or Parkinson’s;

(7) an inability to complete the initial BBS and/or DGI tests; (8) an inability to speak and understand the English language; and (9) internal cardiac devices (pacemakers).

Consent Forms

The form was in English only. Florida Ear & Balance Center, P. A. front desk personnel and James S. Atkins Jr, MD, dispensed the form. The principal investigator answered all questions regarding study eligibility and participant obligation, advised subjects they could withdrawal at any time without penalty, and obtained signatures.[Appendix A] A copy of the executed informed consent was given to the study participant.

Specific Procedures Employed

Protocol

After informed consent signatures were obtained, the initial evaluation session included medical and falls history, MMSE[114] and handheld Snellen vision test, sitting unaided on a 46 cm high bench for 2 minutes, aided or unaided sit-to-stand, and 2 minute steady stance with or without a cane or walker. Subjects meeting the inclusion criteria were randomly assigned to the on-site control group or the device group, both at the Florida Ear and Balance Center, or to the off-site control group at another outpatient physical therapy facility. Subjects not wishing to travel to Florida Ear & Balance Center or subjects requesting a specific physical therapist not employed by Florida Ear & Balance Center, P. A. were placed in the off-site control group. The data collection physical therapist then pretested subjects with BBS, DGI, FIM-Motor, and NeuroCom Sit-to-Stand protocols.

All subjects were then referred for physical therapy intervention prescribed by James S. Atkins Jr, MD. The prescription read as follows: evaluate and treat with inclusion of eyes open/eyes closed steady stance, weight shifting, sit-to-stand to steady stance activities, and a home exercise program. All groups received a total of 6 interventions, with 1-hour sessions 2 times per week for 3 weeks.

In addition to standard care physical therapy, the device group was instructed in the use of the force platform vibrotactile device by the principal investigator. The device was used while performing standard care activities for 1 hour 2 times per week for 3 weeks. Instruction included (1) feedback activities; (2) feedforward activities, both seated and standing; and (3) sit-to-stand to steady stance vibrotactile sway guidance.

All posttreatment testing was conducted at the Florida Ear & Balance Center location at intervals: (1) directly following 2 weeks of treatment, (2) 1 month posttreatment, (3) 3 months posttreatment, and (4) 6 months posttreatment. Posttest data included (1) fall history, (2) FIM-Motor, (3) DGI, (4) BBS; (5) NeuroCom Comprehensive Report; and (6) NeuroCom Sit-to-Stand normative ratio data.

Subjects followed the same test and treatment schedule in Table 1. A written appointment schedule and phone calls reminded subjects of their appointments. Subjects who did not keep appointments after one attempt to reschedule within the same week were dropped from the study.

Table 1. *Evaluation/Intervention Protocol*

Session	Activity
1	Initial Evaluation at Florida Ear & Balance Center
1	Physical Therapy Session 1, Week 1
2	Physical Therapy Session 2, Week 1
3	Physical Therapy Session 3, Week 2
4	Physical Therapy Session 4, Week 2
5	Day 14 Evaluation at Florida Ear & Balance Center
6	Physical Therapy Session 5, Week 3
7	Physical Therapy Session 6, Week 3
8	Day 30 Evaluation at Florida Ear & Balance Center
9	Day 90 Evaluation at Florida Ear & Balance Center
10	Day 180 Evaluation at Florida Ear & Balance Center

Procedures

Each subject was pretested with BBS, DGI, self-report falls, NeuroCom Sit-to-Stand Comprehensive Report, and NeuroCom Sit-to-Stand normative ratio protocol. All physical therapy intervention sessions were 1 hour. The device group was instructed in the use of the force platform vibrotactile device for 10-15 minutes during the first session. Thereafter, steady stance, weight shifting, and sit-to-stand were preformed while wearing the device with comparable physical therapy intervention as the on-site control group 2 times per week for 3 weeks. Instruction included (1) feedback activities both seated and standing; and (2) feedback activities, sit-to-stand to steady stance with vibrotactile guidance. The off-site control group was referred by physician prescription to outpatient physical therapy close to their homes 2 times per week for 3 weeks of standard care treatment. Referral physical therapists were blinded to the study. The physical

therapy prescription for all subjects specified evaluation and treatment with inclusion of eyes open/eyes closed steady stance, weight shifting, sit-to-stand to steady stance activities, and a home exercise program.

Posttreatment testing was conducted at Florida Ear & Balance Center: (1) directly following 2 weeks of treatment, (2) 1 month posttreatment, (3) 3 months posttreatment, and (4) 6 months posttreatment. Posttest data included (1) fall history, (2) DGI, (3) BBS, (4) FIM-Motor, (5) NeuroCom Sit-to-Stand Comprehensive Report, and (6) NeuroCom Sit-to-Stand normative ratio protocol.

On-site Physical Therapy Intervention Protocols

Standard care physical therapy intervention for patients with disequilibrium at Florida Ear & Balance Center, see Figure 7, begins with habituation skills that include an eyes open/eyes closed Romberg (feet together) stand with the patient reducing postural sway. Weight-shifting skills taught to the patient to maintain COG between the feet while shifting the body's center of mass at the hips. Gait strategies focus on normalizing ambulation on an even floor under well-lighted conditions. The patient is taught gaze fixation onto eye-level stationary objects and turning the body in segments such as turning the head while feet are stationary. Sit-to-stand instruction focuses on an individual's variation in performing the task while anchoring the gaze and promoting a forward shift and downward force of the trunk mass. Muscle strengthening in general is multi-joint, closed kinetic chain, for example, step-ups while standing that incorporate an element of postural control for balance. The exercises are progressed by sensory

manipulation, narrowing the base of support when standing erect, combining sensory and base of support manipulation, and finally adding a dual task or cognitive task to postural control.

Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**
Romberg Eyes open Eyes closed Weight Shift Gait Strategies Sit-to-Stand Initiate Home Program.	Sharpened Romberg Muscle Strengthening Hip Weight Shift Strategy Vestibular Ocular Reflex Control	Tandem Walk Weight Shift Accuracy Speed Sway On Target Deceleration Ball Toss	Dynamic Activities Weave Step Forward Reach Step-up Pivot Turn Eyes Closed with Sharpened Romberg	End Range of Weight Shift Unilateral Stand Head Shakes with Static Stand Activities	Review of all previous activities. Solidify home exercise program.

Figure 7. Brief Summary of On-site Physical Therapy Intervention Protocol

<u>Brief Summary of the Device Function</u>

The force platform, software, and tactor belt is an input/output, data generating, and data disbursement device. The physical therapist/operator selects a specific skill set, for example, steady stance. The physical therapist adjusts the limits of stability parameters within each of the 8 quadrants. The subject is instructed in a task. In this example, the instructions include stand steady and quiet the tactors. As the subject becomes proficient, dual tasks are introduced, for example, stand steady, quiet tactors, and reach overhead to adjust an object.

<u>Brief Summary of the Device Skill Sets</u>

Sit-to-stand or other large movement tasks are built on skill sets. (Figure 4) Sit-to-stand phase 1 sitting uses symmetrical limits of stability that are set narrow: the subject is

directed to tactor-quiet. Forward momentum for phase 2 before lift-off requires the subject to activate tactor 1 to tactor-on. Trajectory for phase 3 after lift-off is directed with tactor-variable. Then tactor-quiet cues a slightly wider limit of stability for phase 4 steady stance.

<u>Measurement Instruments and Administration (Data Analysis)</u>

MMSE, 21-item version

The MMSE is a brief, quantitative measure of cognitive status in adults. The evaluator asks common knowledge questions, instructs the subject to remember a short word list, and asks the subject to trace a shape with pencil. This test is used to screen potential investigation subjects' cognition and ability to follow directions.[114]

Snellen Chart (handheld)

This chart is used to measure static visual acuity. Potential subjects were screened for low vision while sitting quietly, holding the chart 10 inches from their eyes, and reading out loud the letters on the chart. A score of 20/60 or lower with corrected vision excluded the subject from this investigation.[115]

BBS

The BBS is a 14-item functional postural control measurement tool designed to differentiate the level of independence of individuals with some degree of balance impairment. An evaluator instructs the subject to perform a task and numerically scores

the proficiency of the subject's ability to perform it. The authors of BBS have concluded that there is a moderate correlation between the BBS and other measurement tools, the level of the individual's care, and predictive ability of falls.[30]

DGI, full 8-activity format

The DGI is a measurement tool used to assess postural stability during gait tasks in adults 60 years and older. The subject is asked to perform a task and the evaluator scores the proficiency of the subject's ability to perform it. The DGI was primarily devised to evaluate subjects with vestibular deficits. DGI is operationalized in this study as a means of associating this study to the inertia sensor study of Wall and Wrisley,[75] and to Oddsson's[36] SmartSock study. DGI specificity and reliability is arguably weak concerning the predictive value of falls. However, ad hoc analysis may yield pertinent correlations.[29]

Falls Questionnaire

The data collector verbally asked the subject to provide the number of fall incident(s) that had occurred over a specific period of time. Clarification by a spouse or caregiver was allowed to assure accuracy of the subject's information. Rate of fall(s) was tallied as a number over time.

Modified FIM-Motor

FIM-Motor (Table 2) is an ordinal 7-point Likert scale that subjectively rates the subject's ability to perform a large movement task. Subjects are instructed to "stand up" from a

sitting position in a standard 46 cm seat height. The evaluator scores the proficiency of the subject's ability to perform the task.

Table 2. *Modified FIM (FIM-Motor)*

Pretest	**Activity Performance**	**Posttest**
1	Maximal Assist (performs less than 25% of task)	1
2	Maximal Assist (performs 25%-49% of task)	2
3	Moderate Assist (performs 50%-74% of task)	3
4	Minimal Assist (performs 75% or more of task)	4
5	Supervision (cueing, coaxing, prompting)	5
6	Modified Independence (extra time, devices)	6
7	Complete Independence (timely, safely)	7

Abbreviation: FIM, Functional Independence Measurement.

PASW Statistics 17 Grad Pack for Word 2007

This software is able to analyze data as descriptive statistics and complex statistical analyses. As a standard tool in today's research community, its power was more than adequate for this investigation.[116]

NeuroCom Activity Force Platform Sit-to-Stand Normative Ratio Protocol

Four measurements were collected from the NeuroCom activity force platform Sit-to-Stand protocol, including (1) seated COG sway velocity and asymmetry; (2) before lift-off weight transfer, (3) after lift-off rising index, and (4) steady stance COG sway velocity and asymmetry. Data collection was directly associated to these study criteria of

sit-to-stand: (1) sit, (2) before lift-off, (3) after lift-off, and (4) stand. An essential assumption is made: force against the ground must be applied to change postural momentum and trajectory. Therefore, the force of gravity, as indicated by the force platform data, is adequate to assess the sit-to-stand task. Each of the 4 domains comprised 3 attempts: the accumulative score is reported as ratio data.[28] If the task was not completed because the therapist used touch to steady the subject, then the task was a no score (N/S) and the default scored applied. See Table 3.

Table 3. *NeuroCom Activity Force Platform Defaults*

Measurement	**Lower/Upper Limits**	**Default (Represents highest score)**
Weight Transfer (s)	0-2.0	2.0
Rising Index (% Body Weight)	0-100	0
COG Sway Velocity (degrees/s)	0-20	20
% Left/Right Weight Symmetry (% Body Weight)	0-59	50

Abbreviation: COG, Center of Gravity.

Subjects were seated on the 43 cm height block bench positioned on the NeuroCom Activity force platform. Subjects were asked to "stand up" when prompted by the computer program: this was repeated 3 times. The scores of the 3 attempts were summed. The physical therapist provided standby or contact guard as needed to keep the patient safe from falling; however, touching the patient invalidated that trial. If the COG was not moved sufficiently forward, the patient could fall back onto the bench. If the COG was moved too far forward, the patient could fall forward. If the trial resulted in a patient

being unable to initiate the activity or requiring contact guard to prevent a fall, then N/S as default score was recorded, see Table 3.

Formats for Presenting Results

This case/control design used (M)ANOVA to compare multiple tests/retests after intervention and over time. Paired sample *t*-tests at 0.95 level of significance compared NeuroCom ratios. The (M)ANOVA design, the representation in Table 4, summarizes trends. Interval data from BBS, DGI, and FIM-Motor were compared pre- and postintervention by (M)ANOVA. The number of falls per participant was treated as interval data, and the Wilcoxon signed ranks test described the degree of association. Within-subject change over time is described with case summary tables.

Table 4. *Formats for Presenting Results*

Instrument	**Level**	**Measurement**	**Score Range**
Berg Balance Scale	Interval	Numerical	0-56
Dynamic Gait Index	Interval	Numerical	0-24
Functional Independence Measurement (FIM-Motor)	Interval	Numerical	0-21
NeuroCom Activity Platform % Body Weight Transfer Sit/ Before Lift-Off	Ratio	Seconds	0-2.0[a]
NeuroCom Activity Platform Rising Index After Lift-Off	Ratio	% of Body Weight	0-100
NeuroCom Activity Platform Center of Gravity Sway Velocity Sit/Stand	Ratio	Distance/Time	0-20
NeuroCom Activity Platform % Left/Right Weight Symmetry	Ratio	% of Body Weight	0-50
Self-reported Falls	Ordinal	Numerical	0-20[b]

[a]A maximal score of 2.0 s was arbitrarily set as an indication of lengthy performance time for this task.
[b]A maximal score of 20 was arbitrarily set for self-reports of multiple daily falls per data collection period.

Evaluator physical therapists were trained until intra- and interclass correlation coefficient (ICC) reached 0.85 kappa for BBS, DGI, and FIM-Motor.

Resources Used

Physical Plant

The clinical office at Florida Ear & Balance Center, P. A. provided office space, clerical staff, and office supplies. Evaluator physical therapists were hired. Study expenses was paid for by the principal investigator.[Appendix B]

Equipment

The NeuroCom Equitest, including the activity force platform and protocols, was provided for use by Florida Ear & Balance Center, P.A. The force platform vibrotactile device prototype was developed by Engineering Acoustics, Inc, and purchased by BalanceSense, LLC.

Reliability and Validity

Reliability

Efforts to control reliability are difficult because tests administered to the subjects are subjectively quantified. Patients as clinical study subjects statistically are considered to be homogeneous, but in reality this is not the case. However, dependent variables BBS, NeuroCom Sit-to-Stand Comprehensive Report, and NeuroCom Sit-to-Stand normalitive

ratio protocol have been selected because of strong specificity and sensitivity validity. The DGI is an exception: this test was selected in order to compare data from this investigation with those of similar studies. The distribution of severity across patients is disclosed with SOT and the NeuroCom Motor and Adaptation scores.

BBS addresses 2 dominions of balance: (1) ability to maintain upright posture and (2) postural adjustments for voluntary movement. Narrowing the base of support and altering sensory input manipulated the degree of difficulty. Timing of movements is considered a marker of postural adjustment for voluntary movement efficiency. Interrater ICC of older adults is 0.91. Test/retest ICC is 0.92 for older adults.

DGI is sensitive to people with vestibular disorders that are at increased risk for falling. The correlation between the BBS and DGI was only moderate, r=0.71; P<0.01; therefore, DGI is thought to measure a different aspect of balance than the BBS. DGI does not have established reliability and validity among community-dwelling older adults.[117]

FIM-Motor assesses disability in terms of burden of care. It is used to monitor patient progress and to assess outcomes of rehabilitation. It is a rating scale applicable to patients of all ages and diagnoses. FIM is based on the Uniform Data System for Medical Rehabilitation to measure disability in terms of life function. It is not a comprehensive instrument but a basic indicator of disability that focuses on the burden of care. The 7-point rating version finds ICC ranging from 0.93 to 0.96: the mean kappa index for each item is 0.71. In general, a change of 1 point on the FIM total score represents 3.8 minutes of care per day.[118] This study uses a small component of the total FIM.

The NeuroCom Comprehensive Report is quantified by the NeuroCom Ratio Scales. ICC does not apply. There was no validation of significance of change.

Self-reported falls are subject to a patient's recollection. In this study, time frames of data collection vary from a pretest interval of 6 months to posttest intervals of 2 weeks, 60 days, and 90 days. For example, the pretest asks subjects to report falls within the past 6 months and the day 14 data collection asks subjects to report falls within the past 2 weeks. Subjects were followed postintervention for 6 months, which mirrors the pretest time frame. The sum of postintervention data (6 months) compared pretest data in an equal time frame.

Statistical methods consider the variability between demographics in a typical clinical setting. Pretest subject inter- and intrahomogeneity was established by Pearson *r*. Power is affected because of sample size, but nonetheless supports the aim of the study. Change over time is the basis of this investigation. (M)ANOVA was used to quantify repeated measure data; paired *t*-test between groups was used to describe interval data; Wilcoxon signed ranks, an alternative to the *t*-test, describes interval self-report falls because the data set cannot be assumed to be normally distributed; and case summaries displayed as frequency tables describe change over time between groups and within cases. Methods are appropriate for this type of data.

Validity

Content validity was strong because the investigation purposely incorporates a clinical setting construct. Subject selection criteria are specific to previously validated large pools of NeuroCom normative data. In that regard, study outcomes may be reliable for similar populations that report falls along with abnormal NeuroCom Sit-to-Stand scores. The sample size construct is adequate for the selected statistical tools. Content is small and diverse. The sample size for power n=63 was not met. Self-reported falls should be regarded as suspect.

Chapter Summary

The study population was recruited and randomly assigned to an off-site control, an on-site device, or an on-site control group. Data included an independent pretest variable and multiple dependent variable posttests.

Procedures for recruitment, enrollment, informed consent, intervention, and data collection were described. Regulatory device classification was explained. Internal review board supervision of patient privacy and safety was described.
Terms were operationalized.

The instruments for data collection were described and were those typically used in rehabilitation settings. Methods for statistical analysis were outlined. Study reliability and validity was described with consideration of internal consistency and instrument validity.

CHAPTER 4: RESULTS

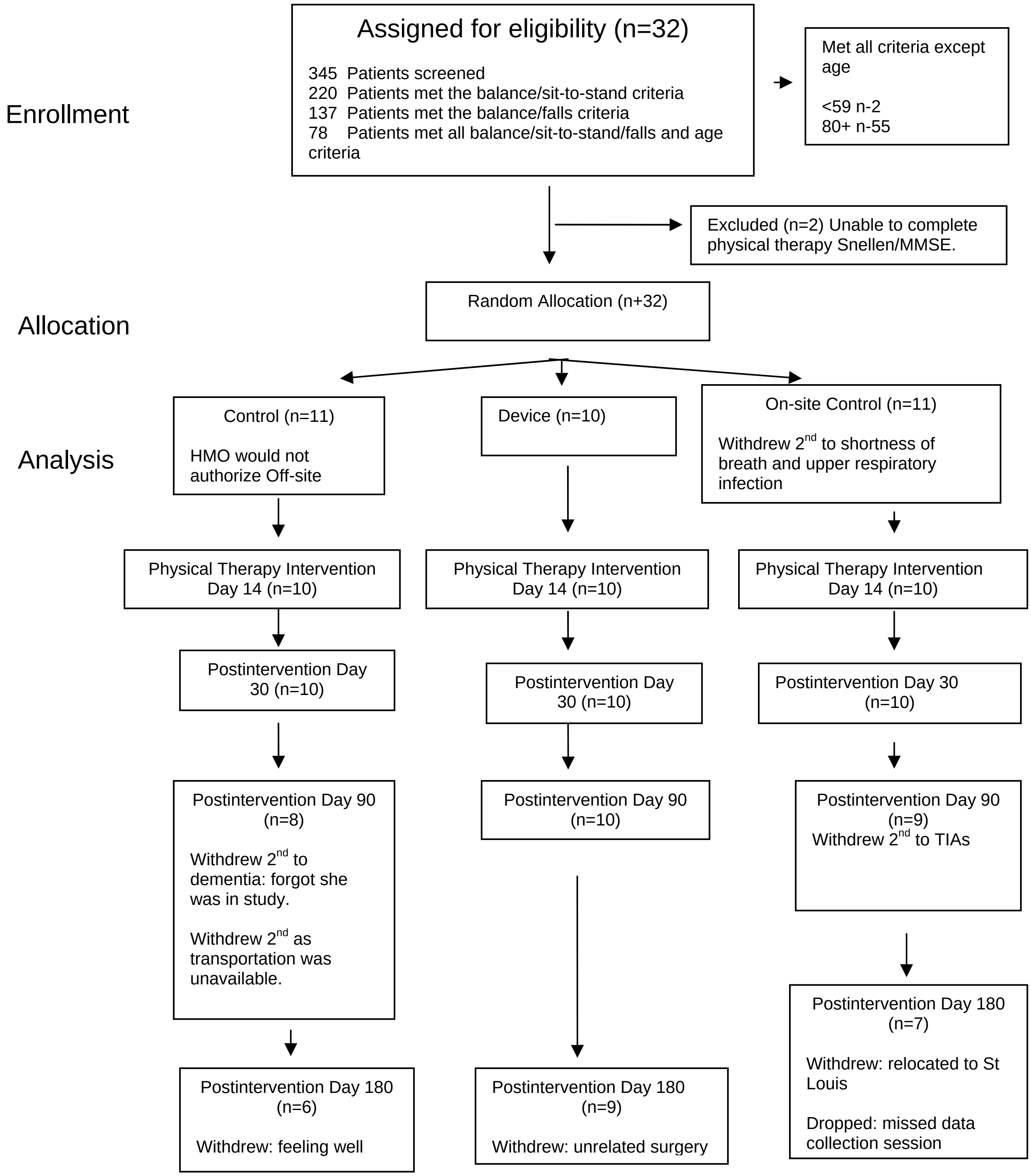
Introduction

Table 5 shows the flow of participants through each stage of the studies and the details of the collected data and analysis. Baseline demographic and clinical characteristics are described and illustrated tables 6 and 7. There were no adverse events or side effects to report.

The on-site physical therapist has 31 years of experience evaluating and treating patients with orthopedic and disequilibrium deficits. In addition, the physical therapist is a retired athletic trainer: patients with neural and sensory disorders and patients with complaints of dizziness, imbalance, and falls have been the physical therapist's focus for the past 14 years.

Thirty subjects, including 11 males and 19 females between the ages of 60 and 79 years, were recruited from a sample of patients with disequilibrium. After meeting inclusion/exclusion study criteria, and signing informed consent, subjects were randomly assigned to 1 of 3 groups: (1) on-site device, (2) on-site control, or (3) off-site control as represented in table 5. Pretest data included patient demographics and preintervention balance and sit-to-stand activity performance. Four repeated measure sets of data were collected postintervention.

Table 5. *Sit-to-Stand Population Allocation*



Abbreviations: HMO, health maintenance organization; MMSE, Mini Mental State Examination; TIA, transient ischemic attack.

Other potential candidates selectively complaining of dizziness but not imbalance were not considered, for example, patients with fluctuating lesions in acute neuronitis, perilymph fistula, or Meniere's disease. Objective tests, including videonystagmography, vestibular evoked myogenic potential, audiograms, electrocochleography, and other audiometrics, were reviewed for diagnosis.

Table 6 displays age, gender, and previous physical therapy intervention. Subjects receiving prior physical therapy were noted. Patients that have had previous exposure to physical therapy may better understand the systems and operations of a clinic or rehabilitation facility, such as scheduling or giving a medical history, and are more comfortable working with therapists who are likely to give verbal directions, touch the patient, and assign exercises to the patient to be practiced at home. This piece of data was not quantified, however, because prior physical therapy intervention was not an inclusion/exclusion criterion.

Table 6. *Gender and Age Distribution*

Group	**Number**	**Gender**		**Mean Age**	**SD**
		Male	Female		
Off-site Control	10	2	8	71.4	4.99
Device	10	4	6	70.2	5.51
On-site Control	10	5	5	71.26	4.84
Total	30	11	19	71.26	5.01

SOT and Neural Adaptation tests (Table 7) give objective data that may be used to devise an evidenced-based care plan. The American Academy of Otolaryngology-Head and Neck Surgery defines Computerized Dynamic Posturography test protocols that consist of the SOT and neural adaptation tests.[119] These protocols are considered to be the "gold standard" in the impairment diagnosis of patients with complaints of dizziness, vertigo, and disequilibrium. Posturography is recognized as an integral component in the disability evaluation of patients with balance or dizziness disorders.[120,121] SOT evaluates vestibular, visual, and somatosensory impairment of patients with peripheral/central vestibular deficits, head injury, and fall risk; of the elderly; and of patients with mobility disorders, including central neural disorders, compensated peripheral vestibular deficits, and dynamic visual acuity and gaze stabilization associated with peripheral/central vestibular disorders. Neural adaptation tests are divided into categories: (1) the Motor Control Test measures automatic timing, strength, and symmetry stabilizing responses to external protuberance, indicating metabolic disease affecting balance and central nervous system disorders; and (2) the Adaptation Test measures the response to irregular and varying support surface conditions, indicating mobility disorders, particularly fall risk for the elderly. Some generalization regarding the test protocols can be made. Specifically SOT measures sensory input, and Neural Adaptation and Motor Control Test as likely associated with motor output.

Older populations tend to accumulate medical conditions. In general, the number of conditions, their duration and severity, and their combination influences overall

functional status. In particular, vestibular disorders, especially vestibular disorders combined with neural and/or musculoskeletal deficits, affect equilibrium.[Appendix C]

Table 7. *Prior Physical Therapy Intervention and NeuroCom SOT, Motor Control, and Adaptation Scores*

Group Characteristics

Group	**Number**	**Previous PT**		**Neural**				**Sensory**	
		No	Yes	No Deficit	Motor Control	Adaptation	Both	SOT	SD
Off-site control	10	10	0	5	1	4	0	49.9	11.89
Device	10	5	5	4	2	2	2	54.3	14.25
On-site control	10	7	3	4	0	2	3	47.4	13.19
Total	30	22	8	9	3	8	5	50.53	13.01

Abbreviations: PT, physical therapy; SOT, Sensory Organization Test.

Data Analysis

Data were analyzed using the PSSW Statistics GradPack 17.0 software package from SPSS, Inc. Pearson *r* described pretest instrument score demographics to establish a relationship between this study population and other studies, in particular those studies that used the BSS and/or DGI as instruments. Differences in postural control performance pretest and physical therapy intervention were investigated using repeated measures (M)ANOVA for each intervention group. In addition, a paired-sample *t*-test was used to measure variance between groups. Null hypotheses were rejected when probabilities were less than 0.005. The Wilcoxon signed rank tests measured nonparametric self-reported

falls. Case summaries assessed individual subject changes in test scores and self-reported falls.

Direction of correlation is important because in some tasks, inversion means that performance of a skill becomes more proficient. This applies to seconds in the Weight Transfer measurement and to sway velocity in the COG Sway Velocity measurement. Faster weight transfer indicates better proficiency; likewise, slower sway indicates better postural control.

Study data collection instruments were selected for their utility in measuring postural control during large movement tasks. The ability to voluntarily control posture is fundamental to large movement mobility tasks such as reaching for objects, transitioning from a seated to a standing position or a standing to a seated position, lowering onto one knee, or walking. In particular, the NeuroCom Activity Platform Sit-to-Stand test quantifies the subject's ability to rise from a seated to a standing position. To achieve sit-to-stand, the body's COG is shifted forward while maintaining centering over the base of support onto the feet, followed by extension of the body to an upright standing position while continuing to maintain COG. The components of sit-to-stand are (1) forward lean weight-transfer time; (2) obtaining erect body position by exerting downward force to rise; (3) controlling sway velocity during the rising phase; and (4) left/right symmetry of the rising force. These measurements are influenced by musculoskeletal, movement control, and balance factors.[28] Table 8 shows the pretest descriptive statistics for all subjects.

Table 8. *Pretest Descriptive Statistics*

Pretest Descriptive Statistics
All Subjects

	N	Minimum	Maximum	Mean	SD
Berg Balance Score Pretest	30	18.00	56.00	43.9333	9.55179
Dynamic Gait Index Pretest	30	2.00	23.00	13.8667	6.43661
FIM-Motor Pretest	30	3.00	21.00	15.3667	5.39785
Weight Transfer Pretest (s)	30	.60	6.00	2.7943	1.78177
% Body Weight Rising Index Pretest	30	.00	96.00	35.1333	26.08175
COG Sway Velocity Pretest	30	8.70	60.00	24.6767	15.41655
% Left/Right Weight Symmetry Pretest	30	5.00	150.00	66.2000	39.25724
Self-report Falls	30	2.00	20.00	10.3000	8.04363
Valid N (listwise)	30				

Abbreviations: COG, Center of Gravity; FIM, Functional Independence Measurement.

Pretest Correlations Between Instruments

Pretest scores within this population (n=30) using Pearson *r* (2-tailed) find significant correlation between BBS and DGI of 0.74 at α 0.01, which is consistent with the literature.[29] A significant inverse correlation was found between DGI and Weight Transfer (seconds) of -0.487 at α 0.01, indicating that sit-to-stand becomes faster as DGI scores improve. Similarly, significant correlation exists between the performance score of FIM-Motor and % Body Weight Rising Index, also known as downward force exerted through the lower extremities, at 0.666 at α 0.01. COG Sway (velocity), an indication of postural control, decreases inversely with a correlation of -0.913 and α 0.01. % Left/Right Symmetry, indicating lateral excursion away from midline during post-lift-off sit-to-stand, inversely correlates at -0.763 and α 0.01, and Weight Transfer, a subject's pre- to post-lift-off erectness of posture, inversely correlates at -0.763 and α 0.01. Pearson *r* also finds significant correlation at α 0.01 within the NeuroCom Ratio test suite: % Left/Right Weight Symmetry to Weight Transfer (seconds) at 0.554; % Left/Right Weight

Symmetry to % Body Weight Rising Index of -0.613; % Left/Right Weight Symmetry to COG Sway Velocity at 0.826. The correlation between FIM-Motor and DGI is 0.403 at α 0.05.

Pretest Balance Scores Within Groups

Test scores and their change over time is the analytical basis for this study. To understand the independent variable, simple analysis of means was calculated for each instrument and arranged per group, see Table 9. The device group had the lowest and most variable BBS (mean=39.50, SD=11.37) and the lowest DGI score (mean=11.7, SD=6.58), with the off-site control having the lowest and most variable FIM-Motor score (mean=13.4, SD=6.81). Therefore, the device group was found to have the poorest balance test scores, and the off-site group the poorest ability to transition from sit-to-stand.

Table 9. *Pretest Balance Test Scores*

**Pretest Balance Test Scores
Within Groups**

		N	Minimum	Maximum	Mean	SD
Berg Balance Score	Off-site	10	31.00	56.00	47.50	8.33
	Device		18.00	52.00	39.50	11.37
	On-site		29.00	54.00	44.80	7.64
Dynamic Gait Index	Off-site	10	2.00	23.00	15.00	6.84
	Device		4.00	22.00	11.70	6.58
	On-site		7.00	23.00	14.90	5.95
FIM-Motor	Off-site	10	3.00	21.0	13.40	6.81
	Device		11.00	21.0	17.30	3.33
	On-site		4.00	21.0	15.40	5.27
Valid N (listwise)		10				

Abbreviation: FIM, Functional Independence Measurement.

A subject's memory over time is always suspect. Self-reported falls as pretest data (Table 10) reflect memory over the previous 6 months. Even though the definition of a fall was read to the subject during the interview, homogeneous data collection cannot be assumed; however, a response of "daily multiple falls" might be an indication of the impact of the problem on activities of daily living. A maximal response of 20 was used as a default.

Table 10. *Pretest Self-Reported Falls*

Pretest Self-Reported Falls
Within Groups

	N	Minimum	Maximum	Mean	SD
Off-site control	10	2.00	20.00	10.00	8.67
Device	10	2.00	20.00	12.40	8.47
On-site control	10	2.00	20.00	8.5	7.26
Valid N (listwise)	10				

Pretest NeuroCom Sit-to-Stand ratio scores (Table 11) found the on-site control group as the slowest but most consistent in transitioning from seated to standing (mean=3.23 seconds, SD=1.71). % Body Weight Rising Index found the device group generating the most efficient but least consistent downward force necessary to attain erect posture (mean=50.3, SD=27.53), the best postural control as indicated by COG Sway Velocity (mean=19.03, SD=6.73), and the best % Left/Right Weight Symmetry (mean=47.5, SD=24.69).

Table 11. *Pretest Sit-to-Stand NeuroCom Activity Platform Scores*

Pretest Sit-to-Stand Ratio Scores
Within Groups

		N	Minimum	Maximum	Mean	SD
Weight Transfer (s)	Off-site	10	1.16	6.00	3.01	1.67
	Device	10	.60	5.06	2.13	1.71
	On-site	10	.83	6.00	3.23	1.92
% Body Weight Rising Index	Offsite	10	.00	66.00	30.40	21.87
	Device	10	22.00	96.00	50.30	27.53
	On-site	10	.00	81.00	24.70	23.53
COG Sway Velocity	Off-site	10	8.70	60.00	24.39	17.45
	Device	10	10.90	33.50	19.03	6.73
	On-site	10	10.00	60.00	30.61	18.47
% Left/Right Weight Symmetry	Off-site	10	5.00	150.00	58.70	41.95
	Device	10	16.00	96.00	47.50	24.69
	On-site	10	51.00	150.00	92.40	37.17
Valid N (listwise)		10				

Abbreviation: COG, Center of Gravity.

Findings

Between Groups

ANOVA compared the association between treatment groups. One-way ANOVA comparing balance test scores of subjects randomly assigned to either off-site control, device, or on-site control groups found no significant difference in BBS, DGI, or FIM-Motor scores on pretest, day 14, 30 days postintervention, 90 days postintervention, or 180 days postintervention. One-way ANOVA (F(2,29)=4.36 comparing component scores of sit-to-stand of subjects randomly assigned to off-site control, device, or on-site control groups found a statistical difference at a .95 level of confidence. This analysis revealed that off-site control subjects had a higher % Left/Right Weight Symmetry at pretest (mean=92.4, SD=37.17) and thus less directed to midline, than did the device group (mean=47.5, SD=24.69) or the on-site control subjects (mean=58.7, SD=41.95).

Within Groups

A paired-sample *t*-test (.95 level of confidence) compared the mean of 2 same-test scores, repeated after time, to determine change within groups. Paired-sample *t*-tests calculated and compared the mean pretest score(s), to day 14 score(s) and to the mean 30-day postintervention score(s).

Balance Scores (Table 12)

The device group realized a 39.5/56 to 51.2/56 mean score increase in BBS (mean=11.7; SD=11.77, α=0.012) from pretest (mean=39.5, SD=11.37) to day 14 (mean=51.20, SD=3.42); the device intervention group realized a mean score increase in DGI (mean=8.10, SD=5.40, 001) from 11.7/24 to 19.8/24 from pretest (mean=11.70, SD=6.58) to day 14 (mean=8.10, SD=5.40); the device group realized a mean score increase in FIM-Motor (mean=2.40, SD=2.41, α=0.012) from 16.40/21 to 19.47/21 from pretest (mean=17.30, SD=3.33) to day 14 (mean=19.70, SD=3.19) and between pretest and Day 14 the device group pretest (mean=11.70, SD=7.93, α=0.001) intervention Day 14 (mean=12.40, SD=8.47), self-report falls decreased from 4.26 to 2.09 day 14 (mean=.70, SD=1.05). A significant decrease was found in pretest (mean=8.50, SD=7.26) self-report falls from 3.7 to 1.0 in day 14 (mean=2.00, SD=6.32) in the on-site control group (mean=6.50, SD=6.45, α=0.011).

NeuroCom Sit-to-Stand Ratio Scores (Table 13)

The on-site control group realized a beneficial skill increase (mean=8.55, SD= 7.95, α=0.012) in % Body Weight Rising from day 14 (mean=34.80, SD=9.77) to 30 days postintervention (mean=44.77, SD=14.38).

Table 12. *Paired Sample* t-*test: Balance Scores and Fall Rate*

To avoid Type I error, alpha is .017 (.05/3)		**Paired Differences**					**t**	**df**	**Significance (2-tailed)**
		Mean	SD	SEM	95% Confidence Interval of the Difference				
					Lower	Upper			
On-site	Berg Balance Score Pretest - Berg Balance Score Day 14	-1.50	4.45	1.40	-4.68	1.68	-1.065	9	.315
On-site	Berg Balance Score Day 14 - Berg Balance Score 30 Days Postintervention	-.250	4.97	1.76	-4.41	3.91	-.142	7	.891
Device	Berg Balance Score Pretest - Berg Balance Score Day 14	-11.70	11.77	3.72	-20.12	-3.27	-3.142	9	.012
Device	Berg Balance Score Day 14 - Berg Balance Score 30 Days Postintervention	-.60	3.89	1.23	-3.38	2.18	-.487	9	.638
On-site	Berg Balance Score Pretest - Berg Balance Score Day 14	-6.10	8.31	2.63	-12.05	-.14	-2.319	9	.046
On-site	Berg Balance Score Day 14 - Berg Balance Score 30 Days Postintervention	-.88	3.55	1.18	-3.61	1.84	-.751	8	.474
Off-site	Dynamic Gait Index Pretest - Dynamic Gait Index Day 14	-3.00	3.43	1.08	-5.45	-.54	-2.764	9	.022
Off-site	Dynamic Gait Index Day 14 - Dynamic Gait Index 30 Days Postintervention	-3.37	3.88	1.37	-6.62	-.12	-2.455	7	.044
Device	Dynamic Gait Index Pretest - Dynamic Gait Index Day 14	-8.10	5.40	1.70	-11.96	-4.23	-4.739	9	.001
Device	Dynamic Gait Index Day 14 - Dynamic Gait Index 30 Days Postintervention			.83	-1.99	1.79	-.120	9	.907
On-site	Dynamic Gait Index Pretest - Dynamic Gait Index Day 14	-4.80	5.95	1.88	-9.06	-.53	-2.547	9	.031
On-site	Dynamic Gait Index Day 14 - Dynamic Gait Index 30 Days Postintervention	-1.33	2.06	.68	-2.91	.25	-1.940	8	.088
Off-site	FIM-Motor Pretest - FIM-Motor Day 14	-3.20	3.85	1.21	-5.95	-.44	-2.626	9	.028
Off-site	FIM-Motor Day 14 - FIM-Motor 30 Days Postintervention	-3.25	6.13	2.16	-8.37	1.87	-1.498	7	.178
Device	FIM-Motor Pretest - FIM-Motor Day 14	-2.40	2.41	.76	-4.12	-.67	-3.145	9	.012
Device	FIM-Motor Day 14 - FIM-Motor 30 Days Postintervention	-.20	4.02	1.27	-3.07	2.67	-.157	9	.879
On-site	FIM-Motor Pretest - FIM-Motor Day 14	-2.80	4.56	1.44	-6.06	.46	-1.939	9	.084
On-site	FIM-Motor Day 14 - FIM-Motor 30 Days Postintervention	-1.55	2.00	.66	-3.09	-.01	-2.325	8	.049
Off-site	Falls(s) Pretest - Fall(s) Day 14	6.70	7.55	2.39	1.29	12.10	2.803	9	.021
Off-site	Fall(s) Day 14 - Falls 30 Days Postintervention	2.62	4.10	1.45	-.80	6.05	1.809	7	.113
Device	Falls(s) Pretest - Fall(s) Day 14	11.70	7.93	2.50	6.02	17.37	4.665	9	.001
Device	Fall(s) Day 14 - Falls 30 Days Postintervention	.30	1.41	.44	-.71	1.31	.669	9	.520
On-site	Falls(s) Pretest - Fall(s) Day 14	6.50	6.45	2.03	1.88	11.11	3.186	9	.011
On-site	Fall(s) Day 14 - Falls 30 Days Postintervention	1.11	6.07	2.02	-3.55	5.77	.549	8	.598

Abbreviation: FIM, Functional Independence Measurement.

Table 13. *Paired Sample* t*-test: NeuroCom Sit-to-Stand Scores*

NeuroCom Sit-to-Stand Ratios Paired Samples Test

To avoid Type I error, alpha is .017(.05/3)		Paired Differences							
					95% Confidence Interval of the Difference				
		Mean	SD	SEM	Lower	Upper	*t*	*df*	Significance (2-tailed)
Device	Weight Transfer (s) Pretest - Weight Transfer (s) Day 14	.85	1.55	.49	-.25	1.96	1.733	9	.117
Device	Weight Transfer (s) Day 14 - Weight Transfer (s) 30 Days Postintervention	.20	1.24	.39	-.69	1.09	.514	9	.620
Device	Weight Transfer (s) Pretest - Weight Transfer (s) Day 14	.85	1.55	.49	-.25	1.96	1.733	9	.117
Device	Weight Transfer (s) Day 14 - Weight Transfer (s) 30 Days Postintervention	.20	1.24	.39	-.69	1.09	.514	9	.620
On-site	Weight Transfer (s) Pretest - Weight Transfer (s) Day 14	.76	2.08	.65	-.71	2.25	1.169	9	.273
On-site	Weight Transfer (s) Day 14 - Weight Transfer (s) 30 Days Postintervention	1.10	2.10	.70	-.51	2.72	1.567	8	.156
Off-site	% Body Weight Rising Index Pretest - % Body Weight Rising Index Day 14	-10.50	12.86	4.06	-19.69	-1.30	-2.582	9	.030
Off-site	% Body Weight Rising Index Day 14 - % Body Weight Rising Index 30 Days Postintervention	-2.87	15.25	5.39	-15.62	9.87	-.533	7	.610
Device	% Body Weight Rising Index Pretest - % Body Weight Rising Index Day 14	4.00	20.04	6.34	-10.34	18.34	.631	9	.544
Device	% Body Weight Rising Index Day 14 - % Body Weight Rising Index 30 Days Postintervention	-7.30	16.04	5.07	-18.78	4.18	-1.438	9	.184
On-site	% Body Weight Rising Index Pretest - % Body Weight Rising Index Day 14	-4.40	18.28	5.78	-17.48	8.68	-.761	9	.466
On-site	% Body Weight Rising Index Day 14 - % Body Weight Rising Index 30 Days Postintervention	-8.55	7.95	2.65	-14.67	-2.44	-3.227	8	.012
Off-site	COG Sway Velocity Pretest - COG Sway Velocity Day 14	7.01	11.89	3.76	-1.49	15.51	1.864	9	.095
Off-site	COG Sway Velocity Day 14 - COG Sway Velocity 30 Days Postintervention	-5.75	29.89	10.56	-30.74	19.24	-.544	7	.603
Device	COG Sway Velocity Pretest - COG Sway Velocity Day 14	.16	8.39	2.65	-5.84	6.16	.060	9	.953
Device	COG Sway Velocity Day 14 - COG Sway Velocity 30 Days Postintervention	.77	10.86	3.43	-7.00	8.54	.224	9	.828
On-site	COG Sway Velocity Pretest - COG Sway Velocity Day 14	6.08	16.30	5.15	-5.58	17.74	1.179	9	.269
On-site	COG Sway Velocity Day 14 - COG Sway Velocity 30 Days Postintervention	2.05	9.28	3.09	-5.08	9.19	.664	8	.525
Off-site	% Left/Right Weight Symmetry Pretest - % Left/Right Weight Symmetry Day 14	23.50	22.61	7.15	7.32	39.67	3.286	9	.009
Off-site	% Left/Right Weight Symmetry Day 14 - % Left/Right Weight Symmetry 30 Days Postintervention	29.42	47.62	16.83	-10.39	69.24	1.747	7	.124
Device	% Left/Right Weight Symmetry Pretest - % Left/Right Weight Symmetry Day 14	2.10	26.21	8.289	-16.65	20.85	.253	9	.806
Device	% Left/Right Weight Symmetry Day 14 - % Left/Right Weight Symmetry 30 Days Postintervention	9.30	32.15	10.16	-13.70	32.30	.915	9	.384

Abbreviation: COG, Center of Gravity.

The off-site control group realized a beneficial skill decrease in mean score for % Left/Right Weight Symmetry (mean=23.50, SD=22.61, α=0.009) from pretest (mean=92.40, SD=37.17) to day 14 (mean=68.90, SD=46.64).

Self-reported Falls

The Wilcoxon signed rank test (Tables 14, 15) is nonparametric and appropriate when normal distribution assumptions cannot be made. It can be used as an alternative to the paired-samples *t*-test for repeated measurements on a single sample.

Table 14. *Wilcoxon Signed Ranks Test Within Group*

Within Group Falls Summary

Off-site Control Group Test Statistics[a]

	Fall(s) Day 14 - Falls(s) Pretest	Falls 30 Days Postintervention - Falls(s) Pretest	Falls 90 Days Postintervention - Falls(s) Pretest	Falls 180 Days Postintervention - Falls(s) Pretest	Post-Falls Total - Falls(s) Pretest
Z	-2.673[b]	-2.524[b]	-2.533[b]	-2.371[b]	-.841[b]
Asymp. Sig. (2-tailed)	.008	.012	.011	.018	.400

Device Intervention Group Test Statistics[a]

	Fall(s) Day 14 - Falls(s) Pretest	Falls 30 Days Postintervention - Falls(s) Pretest	Falls 90 Days Postintervention - Falls(s) Pretest	Falls 180 Days Postintervention - Falls(s) Pretest	Post-Falls Total - Falls(s) Pretest
Z	-2.809[b]	-2.825[b]	-2.823[b]	-2.724[b]	-2.492[b]
Asymp. Sig. (2-tailed)	.005	.005	.005	.006	.013

On-site Control Group Test Statistics[a]

	Fall(s) Day 14 - Falls(s) Pretest	Falls 30 Days Postintervention - Falls(s) Pretest	Falls 90 Days Postintervention - Falls(s) Pretest	Falls 180 Days Postintervention - Falls(s) Pretest	Post-Falls Total - Falls(s) Pretest
Z	-2.675[b]	-2.521[b]	-2.371[b]	-2.375[b]	-1.826[b]
Asymp. Sig. (2-tailed)	.007	.012	.018	.018	.068

a. Wilcoxon signed rank test

b. Based on positive ranks

Table 15. *Wilcoxon Signed Ranks Test Between Groups*

Between Group Falls Summary

Ranks

		N	Mean Rank	Sum of Ranks
Fall(s) Day 14 - Falls(s) Pretest	Negative Ranks	28[a]	14.50	406.00
	Positive Ranks	0[b]	.00	.00
	Ties	2[c]		
	Total	30		
Falls 30 Days Post intervention - Falls(s) Pretest	Negative Ranks	26[d]	13.50	351.00
	Positive Ranks	0[e]	.00	.00
	Ties	1[f]		
	Total	27		
Falls 90 Days Postintervention - Falls(s) Pretest	Negative Ranks	25[g]	13.00	325.00
	Positive Ranks	0[h]	.00	.00
	Ties	0[i]		
	Total	25		
Falls 180 Days Postintervention - Falls(s) Pretest	Negative Ranks	23[j]	12.00	276.00
	Positive Ranks	0[k]	.00	.00
	Ties	0[l]		
	Total	23		

Test Statistics[m]

	Fall(s) Day 14 - Falls(s) Pretest	Falls 30 Days Postintervention - Falls(s) Pretest	Falls 90 Days Postintervention - Falls(s) Pretest	Falls 180 Days Postintervention - Falls(s) Pretest
Z	-4.632[n]	-4.470[n]	-4.392[n]	-4.223[n]
Asymp. Sig. (2-tailed)	.000	.000	.000	.000

:

[a] Fall(s) Day 14 < Falls(s) Pretest
[b] Fall(s) Day 14 > Falls(s) Pretest
[c] Fall(s) Day 14 = Falls(s) Pretest
[d] Falls 30 Days Postintervention < Falls(s) Pretest
[e] Falls 30 Days Postintervention > Falls(s) Pretest
[f] Falls 30 Days Postintervention = Falls(s) Pretest
[g] Falls 90 Days Postintervention < Falls(s) Pretest
[h] Falls 90 Days Postintervention > Falls(s) Pretest
[i] Falls 90 Days Postintervention = Falls(s) Pretest
[j] Falls 180 Days Postintervention < Falls(s) Pretest
[k] Falls 180 Days Postintervention > Falls(s) Pretest
[l] Falls 180 Days Postintervention = Falls(s) Pretest
[m] Wilcoxon signed rank test
[n] Based on positive ranks

Adjusting for self-report from subjects when asked to quantify falls, the Wilcoxon signed rank test provides a narrative description of outcomes. Pretest to day 14 found 28/30 subjects reporting a decrease in falls; however, the interval comparison was the previous 6 months to the past 14 days. Pretest to 30 days postintervention finds 26/27 subjects reporting decreases in falls, and the reporting interval is the previous 6 months (pretest) to the past 30 days. Ninety days postintervention finds 25/25 reporting a decrease in falls for a 60-day period. One hundred eighty days postintervention finds 23/23 reporting a decrease in falls in the past 90 days as compared with the pretest 6-month interval. Total falls for a full 6 months of the clinical trial find 16/21 reporting a decrease, 2 reporting no change, and 3 reporting increases in falls.

<u>Composite Balance Scores Case Summary</u>

ANOVA, paired-sample *t*-test, and Wilcoxon signed rank test have individually found significant confidence levels between and within groups. However, the sum of the 3 interval scales, scored by the data collector physical therapist, see Table 16, is similar to the reporting format in a clinical setting, which in a practical way displays variance between means and Wilcoxon signed ranks narrative. This case summary data set compared pretest to day 14 rates and found the device intervention group had achieved the most beneficial change when comparing a *summed* score of BSS plus DGI plus FIM-Motor.

Table 16. *Sum of Berg Balance Score, Dynamic Gait Index, FIM-Motor, and Change Rate Within Subjects*

Summary of Balance Tests and Rate of Change Within Subjects
Pretest to Day 14

Off-site Control			**Device**			**On-site Control**		
Subject	Rate	Falls	Subject	Rate	Falls	Subject	Rate	Falls
201	9	20/0	301	38	20/3	401	-1	2/0
202	5	20/0	302	8	20/0	403	13	20/0
203	4	3/0	303	6	20/1	404	-2	10/0
204	8	4/3	304	48	2/0	405	49	4/0
205	-1	6/0	305	7	2/0	407	17	3/0
206	3	3/0	307	15	4/0	408	8	5/0
207	10	2/0	308	5	4/0	409	6	3/0
210	26	20/10	309	41	20/0	410	14	15/0
211	10	2/0	310	29	12/1	411	31	20/20
212	4	20/20	311	15	20/2	412	3	3/0
Average	7.8	9 decreased		21.2	10 decreased		13.8	9 decreased
		1 unchanged						1 unchanged

	Minimal	Maximal	Mean
Total Score	0	101	50.5
Change Range	-2	49	25.5
Off-site	-1	26	12.5
Device	5	48	21.5
On-site	-2	49	23.5

<u>NeuroCom Comprehensive Report Summary</u>

The NeuroCom Sit-to-Stand Comprehensive Report pictorially displays NeuroCom normative ratio tests. Abnormal performance per age norms is represented by dark shaded areas. Please see page 16. Subject eligibility required abnormality in at least one of the Weight Transfer, % Body Weight Rising Index, COG Sway Velocity, or % Left/Right Weight Symmetry domains. A summary of Sit-to-Stand domains was reported as normal/abnormal in the comprehensive report. Case summaries found that the

rate of falls does not correlate to a change in the NeuroCom Comprehensive Report normal/abnormal or abnormal/normal status.

Falls Between Groups Over Time

Self-report fall data was collected over varying lengths of time. Subjects were asked to self-report pretest number of falls for the preceding 6 months. Comparing pretest to the accumulative postintervention time finds then an equal six month reporting period, see Figure 8. The off-site control group reported an increase in falls, the device group reported a decrease in falls, and the on-site control group reported a decrease in falls during the 6 month posttest data collection period as compared to the pretest report. Subjects were aware that fall rate would be collected during each data collection session. The summed total of falls from the six months study duration could be thought to be more accurate than the pretest report.

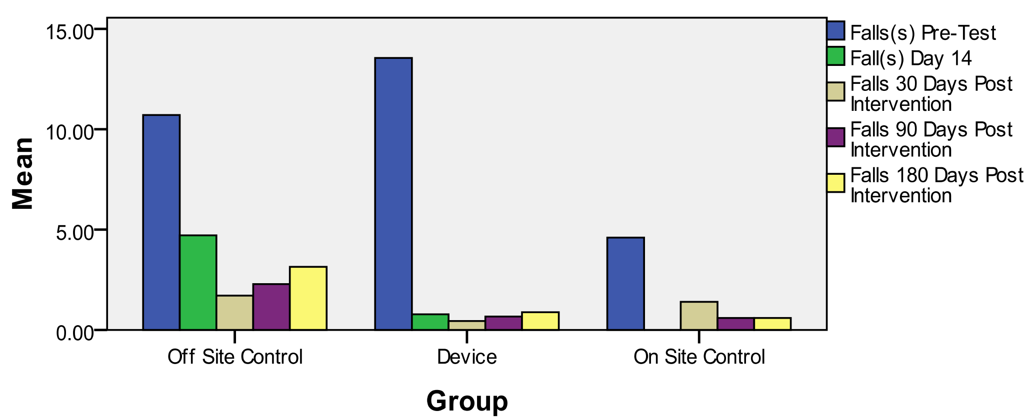


Figure 8. Comparison of Fall Rates

Summary of the Results

Population

The study is a case control, repeated measure design of 30 subjects comparing standard care physical therapy plus treatment with the force platform vibrotactile guided mobility device to standard care physical therapy only. This was the first study that used a vibrotactile device on clinical patients in a physical therapy clinical setting with standard care rehabilitation.

Research Question

In a population aged 60 to 79 years with abnormal NeuroCom Sit-to-Stand scores and 2 or more self-reported falls within the past 6 months, does the population receiving standard care physical therapy plus vibrotactile force platform device intervention improve postural control and decrease fall rates faster and better than controls receiving standard care physical therapy only?

Outcomes

Thirty subjects, 11 male and 19 female, aged 60 to 79 years (mean=71), were selected from a population of patients being seen by a physician for complaints of disequilibrium, including imbalance. Preintervention SOT found scores between 31 and 74 (mean= 50). Neural test scores found 3 patients with motor control deficits, 9 with adaptation deficits, 5 with both motor and adaptation deficits, and 13 with no Motor Control Test or Adaptation Test score deficits. The self-reported number of medical complaints found a

mean of 3.4 and a range of 1 to 7, with hypertension as the most prevalent; 8 subjects had received prior physical therapy intervention but not necessarily for balance issues. Statistical correlation between groups and within cases could not be established for the relationships between age, gender, SOT, Motor Control Test, Adaptation Test, prior physical therapy, medical conditions, and self-reported falls. This population found a correlation between BBS and DGI scores similar to other study populations.

Pretest balance tests found that the device intervention group had the poorest balance scores and the highest self-reported number of falls. Day 14 and 30 days postintervention scores found the device intervention group had the most improved balance suite scores and the greatest decline in the fall rate (significant at a .95 level of confidence). Hypotheses 1 and 3 retain H_1 and reject H_0.

There was significant beneficial effect between standard care physical therapy and sit-to-stand ratio scores, including % Body Index rising for the on-site control group and the % Left/Right Symmetry for the off-site control group. Hypothesis 2: H_1 is rejected and H_0 is retained.

There was no relationship between standard care physical therapy plus vibrotactile device and NeuroCom Sit-to-Stand normative ratio scores. Hypothesis 4: H_1 is rejected and H_0 is retained.

There is a relationship between standard care physical therapy plus treatment with the vibrotactile device and standard care physical therapy only. Summation of balance test scores and self-report falls finds a significant, beneficial effect between the device intervention and control groups. H_1 is retained.

DGI specificity indicates that scores of less than 20/24 have been related to reported falls in community-living older adults.[97,122] Similarly, the BBS reports that 45/56 is a generalized cutoff score to predict falls in elderly persons.[123] NeuroCom Posturography SOT has also been found to be a sensitive tool to identify those at high-risk of recurrent falls.[124] If DGI scores and BBSs are elevated faster than traditional physical therapy intervention, then successful application of force platform vibrotactile intervention could change the approach of physical therapists to rehabilitate their patients who fall.

Older adults with abnormal sit-to-stand and self-reports of fall(s) were able to improve balance test scores faster and better with physical therapy standard care plus treatment with the vibrotactile force platform device than were those receiving standard care physical therapy only. However, all subjects improved in BBSs, DGI scores, and FIM-Motor scores, consistent with other studies.[2] Likewise, knowledge transfer was demonstrated by most improvement in postural control in the device intervention group as evidenced in improvement in FIM-Motor scores and reduction in self-report fall rate. Knowledge retention was demonstrated by the rate of change over time study design, and all subjects retained their higher balance scores from pretest to participation conclusion.

The subject attrition rate was 26%.[Appendix C] Withdrew and withdrawals were not related to the study. Only 1 subjected sited transportation as an issue, and 8 subjects reported change in medical status ranging from feeling better to non related surgical procedures.

CHAPTER 5: DISCUSSION

Introduction

This is the first time that the vibrotactile force platform device has been integrated into a standard of care physical therapy setting. Interpretation of results, external validity within the study, applicability to other populations, and general interpretation of the study results will be discussed. The study data first established the pretest variability between groups. Intervention effect over time was measured between groups and within groups. Parametric and non parametric analysis was used to compare standard care physical therapy and standard care physical therapy plus device intervention in patients with balance disorders.

The device was integrated into an existing clinical setting. Physical therapy concerns centered on continuity of optimal patient treatment, acceptance of the device by the patient, and mitigation of adverse effect. Equipment concerns such as tactor belt size, device breakdown, and force platform size were addressed by the engineers. Upgrades to hardware and software were made 2 times during the study. The force platform became smaller and lighter and software added "user friendly" features. However, the data displays and protocols did not change. Measurement of device change impact was beyond the scope of this investigation. The device performed appropriately during all patient treatment sessions. In addition, subjects expressed their opinion of the device which was overwhelming positive.

Results Interpretation

Patient treatment studies can be easily criticized, beginning with the assumption that a population of convenience is homogeneous, to the argument that the null hypothesis really means that no difference exists between the treatment and control groups. Especially when "self-report" is an independent variable, quantifying exactly what is meant by a particular "report" is nearly impossible.

Internal Consistency

Internal consistency was managed from several directions, beginning with clinical site systems and operations. Study access by prospective subjects and intervention scheduling was designated to 1 front desk employee. The physical therapy intervention protocol was directed by prescription from James S. Atkins Jr, MD. Physical therapy progress reports were reviewed weekly. Considerable attention was directed to optimal patient care in all settings, and deficiencies were corrected immediately.

Bias was controlled by a predetermined method of group assignment. Allocation concealment was implemented by assigning patients to device or control groups based on the last digit of their primary phone number, except for those potential subjects who requested physical therapy nearer their home: they were assigned to the off-site control group. Subjects did not have foreknowledge of device vs control treatment assignment. To maintain intervention group balance, a filled group was closed at 10 subjects. Therapists providing treatment were aware of their patients' study participation.

Therapists not providing intervention collected data and were blinded to group assignment.

Measuring balance can be challenging. Study measurement instruments were selected to reflect standard care perception of successful functional ability vs individual style and successful adaptation. For example, BBS, DGI, and FIM-Motor are rater subjective scores based on second-party observation and perception of what a successful functional task should look like: walking from point A to B should be a straight line. Raters were all previously familiar with these tests: there were differences in skill interpretations. Even though ICC was established, the evaluators were instructed to consistently select the lower score if unsure of the patient's proficiency.

Default scores were used to standardize data collection. Subjects reporting daily falls, especially when recalling the previous 6 months as requested for the pretest, were understood to mean multiple falls over time. In addition, subjects unable to perform sit-to-stand on the NeuroCom activity platform without contact assistance were given no score (N/S) and defaulted to the worst performance score available on the summary.

Conversely, the NeuroCom activity platform quantified the task and rendered a ratio score and graphic interpretation of normality without rater interpretation. FIM-Motor was scored concurrently. To enhance reliability of NeuroCom Sit-to-Stand normalitive ratio scores, the 3 trials were summed rather than averaged. NeuroCom Comprehensive Report scores reflect the success of each trial but not performance task consistency. For example,

a "fall" in 1 attempt would result in averaging of the remaining 2 successful scores. Therefore, to obtain a comprehensive view of sit-to-stand from data collected on the NeuroCom platform, task performance must include both measurement designs.

Device intervention and on-site control subjects were instructed by the same physical therapist. These subjects used the NeuroCom dynamic surface and surround platform while practicing weight shifting activities because this was standard of care for this facility. To retain change over time accuracy, subjects were neither instructed in, nor practiced collection of, test activities, for example, sit-to-stand, forward reach, or step-up-and-over, on the NeuroCom equipment. Off-site controls were instructed by other physical therapists using a prescribed protocol outline: not noted was the level of therapist proficiency, ancillary equipment, or level of adherence to prescribed protocol. Patient progress notes from off-site therapists were reviewed for minimal prescription adherence: 1 off-site subject was reassigned to another therapist because the original therapist was not following the prescription.

The device is an intuitive, nonintrusive display designed for training patients with balance deficits by providing immediate and consistent sway data comprising sway, velocity, and trajectory. The device quantifies balance by measurement of body sway in terms of displacement of the COP. COP is computed from force transducers that are typically embedded in the 4 corners of a support surface. Intervention subjects wearing the device while they were instructed in weight shifting and functional activities were instructed to focus on center-of-foot pressure as they performed an activity.

External Consistency

Subjects were recruited from a sample of patients seeking medical intervention for disequilibrium, but many subject characteristics, such as multiple medical conditions, are typical of older populations. Of interest was the reason for study withdrawal: most subjects cited a change in medical status.

Implications

The results of this study show that vibrotactile technology can be effectively incorporated into a physical therapy workflow and treatment plan of care. Introduction of vibrotactile technology into standard care physical therapy is a paradigm shift in treatment strategies. As a sentinel study, this beneficial outcome encourages further investigation(s) of the effect of vibrotactile force platform intervention in other studies and on other populations.

Comparison to Other Vibrotactile Postural Control Devices

Vibrotactile postural hardware and accompanying software are being applied to other prototype balance devices. They appear to provide beneficial effect as indicated by positive measures of sensory and motor testing. As previously cited, Wall, Goebel, and Sienko have demonstrated improvement in SOT by vibrotactile cueing; Allum, Oddsson, Horak, Wrisley, Dozza, and Asseman demonstrated the benefit of vibrotactile cueing in upright functional activities. The device used in this study not only provided sway data typical of that in the other devices, but also applied preprogrammed skill sets to sit-to-

stand. All of the studies showed that the use of vibrotactile cueing had a significant effect upon postural control.

The design of the vibrotactile device used in this study used center of pressure referenced to gravity. Based on the encouraging results, extension to other large movement tasks in impaired subjects is warranted.

Study Design Considerations

NeuroCom Sit-to-Stand measurements were not helpful when determining device effect on normative criteria. Subjects used various movement strategies to achieve the task some of which might be described as atypical of preconceived best practice. Rather than relying on single variant models currently quantified in the NeuroCom Sit-to-Stand protocols, a multivariant model focusing on the task completion, and as measured by FIM-Motor, would better indicate functional mobility outcome.

Device Design Considerations

To better quantify multivariant skill sets, objective test protocols need to be developed with focus on sway, velocity, cadence, trajectory, and time on target. This would be achieved win the device software as specific to a skill set needed for a particular

Efficacy and Safety

Other researchers within the medical sector have begun to address balance deficit by developing devices that provide additional sensory enrichment. Outcome measures in this

study are inadequate for comparing other studies; however, it is prudent to acknowledge that the clinical setting experience of the patients in this study may not have been unlike other subjects' experience. The vibrotactile device is in early research stages: the FDA categorized the device as nonsignificant risk, Class II. There were no adverse effects reported during this study. This is consistent with Wall's studies over the past 3 years.

Best Practice Protocol

Of note, but beyond the scope of this study, was the variation in physical therapy standard care for patients that fall. The device affords an opportunity to standardize evaluation and treatment protocols into skill sets with progressive levels of difficulty based on postural control of sway. Likewise, sway and limits of stability measurement, such as pixel count, should be calibrated with NeuroCom as the gold standard.

Alternative Rehabilitation Perspective for Patients With Postural Control Deficits

Consistent, repetitious, meaningful vibrotactile feedback is currently not available in standard care physical therapy. The importance of brain plasticity models for task learning and relearning is becoming more evident as imaging techniques become more refined. The ability of the brain to reorganize and relearn is a result of a hierarchy of skill sets integrated within functional activities, including control of sway, velocity, and trajectory. Vibrotactile data displays are poised to exploit brain plasticity theory.

Challenges in Falls Intervention

Fall incidence was looked at differently in this study. Rather than reporting fall risk factors, actual rate of fall was quantified. The study acknowledged the presence of differential diagnosis originating from the vestibular, somatosensory, central, and

peripheral neural system, but assessed the extent of disability by evaluating the subject's postural control of sway during functional activities, including feedback static and small movement tasks to feedforward large movement tasks. Some subjects demonstrated that promoting a nontraditional sit-to-stand strategy of lateral asymmetry resulted in achieving the sit-to-stand task. The learned response from feedback promoted feedforward postural control. Approaching balance from a multivariant postural control model, thus accounting for variances in individuals, and using gravity as a reference constant, could be successful in reducing falls.

Recommendations

Other studies on like populations should include larger sample sizes, a narrower scope of investigation, and shorter study duration. Simpler data collection instruments focusing on sway feedback and feedforward movement tasks would be appropriate for vibrotactile cueing. In addition, other movement disorders requiring postural control of sway should be considered. The vibrotactile force platform device in this study found positive effect: this center of pressure approach warrants further study.

Limitations and Delimitations

Limitations

Limitations of the study included a small sample size with attrition. Multiple testing with the same test protocols may have unintentionally measured learning effect. Holding to the

data collection and the intervention schedule was rigorous and challenging. Some data are missing: to avoid skew, missing data points were not replaced statistically. Incorporating several clinical settings resulted in variances in treatment. Intervention protocols followed a general scheme but were tailored to the individual. Consistency of intervention at 1 off-site location could not be controlled.

Delimitations

In general, subjects appear to be representative of older community-dwelling populations. Most subjects kept appointments and showed interest in following through with home exercise programs. Counting falls rather than inferring likelihood of falling from surrogate balance scores accurately distinguishes those who are falling from nonfallers. Extending the study over 7 months allowed comparison of falls to the pretest time frame. The force platform vibrotactile device functioned appropriately and was available for all sessions. A similar study design could be reproduced and implemented with improvements at another location.

Study Summary

A randomized, case/control repeat measure design compared standard care physical therapy plus treatment with the force platform vibrotactile guided mobility device to standard care physical therapy only. Thirty subjects with abnormal sit-to-stand and self-report of 2 or more falls within the previous 6 months were assigned to off-site control, device, and on-site control groups. BBS, DGI, FIM-Motor, NeuroCom Comprehensive

report, NeuroCom normative ratio score, and self-report fall(s) were quantified. The device intervention group was shown to have greater beneficial effect, as evidenced by increased balance test scores and decreased self-reports of falls. The success of this study could change the way physical therapy intervention is delivered to patients with postural control deficits. Useful experience was gained from this study. The results were encouraging, although further studies are needed to confirm the effectiveness of standard care physical therapy plus treatment with the vibrotactile force platform device.

The results off the present study are encouraging, although further studies are needed to confirm the effectiveness of the standard of care physical therapy plus treatment with the vibrotactile force platform device.

Appendix A

Internal Review Board

<u>Informed Consent Protocol</u>

James S, Atkins Jr, MD gave the informed consent form to interested prospective subjects to read. The prospective subjects were asked to decide whether or not to schedule a return appointment as a potential study subject, or to decline the study and schedule physical therapy through traditional channels. The patient was assured that should he/she choose not to take part in this study, the relationship with James S. Atkins Jr, MD, or the Florida Ear & Balance Center, P.A., physical therapists would not be damaged. The patient was also advised that he/she was able to receive physical therapy prescribed by James S. Atkins Jr, MD, at any outpatient physical therapy facility, including Florida Ear & Balance Center, regardless of study status.

To minimize coercion and to allow any potential subject to carefully consider participation, study appointments were scheduled at least 10 days after the invitation to participate. When the potential subject was reminded about their appointment, usually the day before via phone by the front desk staff, he/she was instructed to bring the completed informed consent to the appointment and verbally prompted to ask questions concerning the study. Any questions regarding attire, location, length of appointment, billing, or insurance concerns were addressed by the front desk staff. Medications, medical diagnosis, or test result questions were answered by the office nurses; study participation questions were directed to the principal investigator. The primary investigator reviewed

the informed consent with the prospective subject at the beginning of the first appointment and obtained a signature acknowledging understanding of participation requirements and consent to participate. The informed consent was signed by the participant, witnessed, and signed by the principal investigator before obtaining prestudy measurements, evaluations, or intervention. As acknowledged in the informed consent, the participant's signature indicated that all questions had been answered to satisfaction.

Information Privacy

All personal health information (PHI), including patient medical documentation, were handled in accordance with established office procedures that have previously been found HIPPA compliant. DVD video recording with sound was taken during evaluation and treatment at the Florida Ear & Balance Center location. The video was not transcribed. The chart, including DVD video, will be kept securely in a locked room at Florida Ear & Balance Center for 3 years, after which the chart, including the video, will be professionally stored off-site for an additional 7 years and destroyed after that time. The study information, including the video, may be used for up to 7 years.

Confidentiality

Only the principal investigator, research assistants, select Nova Southeastern faculty, IRB staff, and others as required by law may know the identity of the subjects. The results of the study identify subjects by numerical code: results reported in a dissertation paper, medical journals, educational sessions, or at meetings maintain secrecy of the subjects' identity.

Liability

Karen Hastings Atkins was the sponsor of this research. Neither James S. Atkins Jr, MD, nor Florida Ear & Balance Center, P.A., nor Nova Southeastern University sponsored this research. They were unable to offer financial payment or to pay for the costs of medical treatment to subjects taking part in this research.

Accordingly, the Florida Physical Therapy Practice Act (FS 486) defines Karen Hastings Atkins' role as a physical therapist in this study as within the scope of practice, and thus coverable by her professional liability plan underwritten by American Casualty Company of Reading, Pennsylvania. Nova Southeastern University Department, Health Professions Division, College of Allied Health was listed as additional insured on the Florida Ear & Balance Center, P.A., liability policy by Kuykendall Gardner & Laure LLC for Accord.

Adverse Events

Provisions for managing adverse events at Florida Ear & Balance Center included a physician on site and medical facilities next door available for treatment, as was reasonably possible. James S. Atkins Jr, MD, offered his physician services free of charge to injured study subjects. If the subjects were to have been injured at another outpatient facility, the facilities' policy and procedures took precedence. Subjects were responsible for these costs. However, costs may have been covered, at least in part, by most major insurance companies and Medicare.

Unanticipated problems and adverse events were to be reported to the IRB within 5 working days. Serious adverse events were to be reported to the IRB within 24 hours. There were no adverse events.

Risks to Subjects

Although HIPPA and PHI procedures are adequately in place at the study site, as exemplified by certificates of compliance, and all investigators and dissertation committee members named earlier have run previous clinical trials, there always remains a possibility that subject confidentiality could be compromised. In this event, the principal investigator would have informed the subject(s) immediately about the breach. The dissertation committee would have decided how the study should proceed henceforth.

Risks that were unique to this study are standard for CVA patients and older patients with imbalance. Even though the subjects were given one-on-one instruction from a licensed physical therapist, there was a rare risk that the subject could:

- fall during evaluations or physical therapy sessions
- feel faint or dizzy when bending forward
- feel dizzy when turning

To minimize these risks, only licensed physical therapists working within their scope of practice evaluated and treated study subjects.

There was a rare chance that a subject would fall while being evaluated or trained. If a fall occurred, the physical therapist was to assess the subject's status and obtain medical care as indicated. There was a possibility that subjects would continue to fall outside of the clinical setting at their prestudy participation rate. If substantial injury occurred that disrupted study protocol, then the subject had to withdraw from the study. Their data were still included in the study analysis and reports.

If the subject had a history of syncope, then there was a mild to moderate likelihood that the subject would feel faint or dizzy when bending forward to retrieve an object from the floor. The sensation should have been brief. If the faintness or dizziness did not immediately subside, then the physical therapists sat the subject and monitored blood pressure and pulse rate. The subject could continue the session if blood pressure was lower than 150/90 and the heart rate less than 120 and regular or usual irregular in subjects with known cardiac arrhythmias.

Dizziness and disequilibrium could occur when turning, usually in subjects with vestibular or inner ear disorders. There was a slim chance that the dizziness would continue after the completed activity. If the dizziness continued, then Dr James Atkins was notified so that the subject could be medically managed, most likely with medication. Only prolonged and disabling dizziness would have caused the subject to withdraw from the study.

Prior to seeing study participants, physical therapist data collectors and referral physical

therapists were warned of these risks and advised that complaints of dizziness and syncope would be medically managed by Dr James Atkins. The principal investigator initiated the adverse effect protocol if a fall occurred with or without injury during an evaluation session or training session at the Florida Ear & Balance Center site or if protracted syncope or dizziness requiring hospitalization occurred during an evaluation or training session regardless of the site.

Benefits to Subjects

There were no guaranteed benefits to the subject for taking part in this study. However, if effective, the postural control device could decrease individual fall rates and improve balance test scores faster and better than standard care physical therapy. The device could help maintain balance skills longer than standard physical therapy. In addition, all study participants received evaluations at no cost to them from physical therapists concerned about their balance and falls. Furthermore, previous related intervention studies have shown that frequently reminding subjects to be careful can reduce falls.[2]

Cost to Subjects

*S*ubjects were actual patients referred for physical therapy services. The force platform vibrotactile treatment was added value to standard care. Standard payment fees were collected by Florida Ear & Balance Center, P.A., for intervention subjects and per institution for standard care controls. Insurance and other third-party specifications regarding reimbursement for patients involved in investigative study were strictly adhered to.

Risk/Benefit Ratio

The overall risk to study subjects was minimal and standard for their medical condition. The dependent variable was the device only. The device's vibrotactile display was similar to being touched or tapped, which is a common ploy frequently used by physical therapists. Moreover, all of the data collection instruments were regularly used in rehabilitation.

There was an innocuous risk over benefit ratio for this study. Subjects were performing everyday tasks in a controlled setting. The addition of the device was a more precise way of delivering and displaying balance information through a physiologic system developed to receive tactile data. In addition, accessorizing repetitious large movement tasks added a fun element, as it gave immediate postural control feedback.

Previous studies by Wall have found, however, that incorrect sway feedback can increase imbalance during that particular task.[14] The force platform, software, and tactor belt is an input/output or data generating/data disbursement device that was preset with best practice parameters. The physical therapist/operator selected a specific skill set, for example, steady stance, based on her own subjective decisions regarding protocol for the subject to obtain that skill. This new device, and, accordingly, the therapist, may not have always selected optimal protocols for maximal gain.

Benefits to study participants in the populations included obtaining additional data about their imbalance, particularly as it pertains to activities of daily living and likelihood of

falling. In addition, the attention from physical therapists to the population was extended over a substantially longer period of time than is the case with traditional physical therapy.

Subject's PHI

Personal medical history was obtained by questionnaire for study participants that were referred only for the study. New or returning patients of James S. Atkins Jr, MD, completed a study health history questionnaire that was verified by the medical records of James S. Atkins Jr, MD. Any discrepancies were discussed with the subject. This included name, address, telephone number, date of birth, past medical history, the results of previous objective testing, and evaluations done during this study.

Once PHI was shared with others, it was no longer protected by HIPAA law. However, PHI was coded and kept as confidential as possible. If the potential subject was not willing to allow PHI to be shared, then he/she was not asked to take part in this study.

Classification of the Device: Nonsignificant Risk Class II

The vibrotactile system for the treatment of balance disorders follows the criteria for an insignificant risk. FDA language regarding risk, as well as background and significance on efficacy and safety for the treatment being performed with the device, follows.

Overall, the device is relatively straightforward: COP data obtained from a force measuring platform are displayed to the subject via vibration. Both the force measuring platform (890.1575) and Therapeutic Vibrator (890.5975) are listed in the FDA Product

Classification Database as 510(k) exempt. Data are transferred from the measuring platform to the vibrating C2 tactors through a computer software interface and controller. The C2 tactor specifications are specific to criteria substantially equivalent to a predicate device in 21 CFR 890.5660 (Therapeutic Massager) and CFR 890.5975 (Therapeutic Vibrator), which finds classification of the predicate device Class II standards as reference to 21 CFR and section 513, physical medicine devices panel 89 of the Food, Drug, and Cosmetic Act. In our application, C2 actuators drive at 250 Hz sinusoidal, 300 ms to 500 ms on and with a peak displacement of about 300 microns. The pulse rate is between 1 and 3 seconds and the overall duty cycle is less than 10%. The force platform is stainless steel, with 4 load sensors in each corner: it can easily handle 180 kg.

The Bluetooth controller is self-contained and battery powered (2400 mAH, 9.2 V DC, NiMH battery.) The C2 tactors are hardwired to the controller and thus the Bluetooth interface extends from the D Link inserted in the computer to the tactor controller. Our system stored the controller in a pouch positioned at waist height in the proximity of the lower back.

There appeared to be conflicting opinion regarding Bluetooth safety in a medical environment. Previous investigation found that Bluetooth emission could interrupt internal cardiac devices if placed within 8 to 15 cm, and external dispensers and monitors if in close proximity.[125] To assure that pacemakers and any other like device were uninterrupted, the subject's medical history included specific questions regarding electronic medical devices. In addition, a warning prompt, "Do not use on subjects with

pacemakers. This equipment is not to be used in an ICU setting" appears when a new subject file was selected and must be acknowledged by the device operator by clicking OK. Pacemaker exclusion is included on the study protocol and informed consent.

An infrared remote control such as used as a TV channel changer accompanied the computer for the purpose of distantly changing software settings. This allowed the operator to retain standby guard by the subject at all times. By binding the remote control to a stable, nontilt, or rotating force platform, subject harnessing was not necessary.

Device software was able to (1) limit postural sway by indicating to the wearer static stance by decreasing COP parameters; (2) enhance limits of stability by increasing COP parameters; (3) steer postural trajectory; (4) direct movement cadence; (5) record COP, trajectory, and cadence; and (6) display prerecorded movement pattern data on both the computer screen and through the C2 tactors. These movement patterns are found in activities of daily living and performed multiple times throughout the day by all prospective study participants.

The guidelines from the FDA Web site regarding the necessity for an Investigational Device Exemption (IDE) have been reviewed. Nova Southeastern University has indicated that the vibrotactile device used in this study meets these guidelines.

Internal Review Board (IRB)

This study was approved by Nova Southeastern University IRB, allowing enrollment to commence April 10, 2008, and resubmit extended study approval to April 9, 2010.

Appendix B

Budget

Contract Physical Therapists				
	Initial Evaluations	32 hours	@ $50.00/hr	1,600
	Follow-up Evaluations	128 hours	@$50.00/hr	6,400
Support/Clerical		144 hours	@$30.00/hr	4,320
Equipment				11,800
Physical Plant			In Kind	0
			Total	$ 24,120

Appendix C

Medical Conditions and Withdrawals

Subject	Group	Total Med	Hypertension	Cardiac	Diabetes	Cancer	Respiratory	Neurologic	Joint	Vestibular	CVA	Stomach	Kidney	Allergies	Status
201	Off-site Control	3	Yes	None	None	None	None	None	None	Central	Stroke	No	No	No	Complete
202	Off-site Control	1	None	None	None	None	None	None	None	Perpherial	None	No	No	No	FeellingWellWithdrew
203	Off-site Control	3	Yes	None	None	None	None	Central Processing	None	Perpherial	None	No	No	No	SubjecDropped: Demetia
204	Off-site Control	5	None	Yes	Yes	None	Non-specifi	None	None	Perpherial	None	Yes	No	No	Complete
205	Off-site Control	4	Yes	None	Yes	None	Non-specifi	None	None	Perpherial	None	No	No	No	Complete
206	Off-site Control	6	Yes	Yes	Yes	Inactive	None	None	None	Perpherial	None	No	Yes	No	Complete
207	Off-site Control	3	Yes	Yes	Yes	None	None	None	None	Central	None	No	No	No	Withdrew transportation
210	Off-site Control	1	None	None	None	None	None	Central Processing	None	None	None	No	No	No	Complete
211	Off-site Control	4	Yes	None	Yes	None	None	Central Processing	None	Perpherial	None	No	No	No	Complete
212	Off-site Control	5	Yes	Yes	None	None	Non-specifi	Central Processing	Yes	None	None	No	No	No	Complete
301	Device	7	Yes	Yes	None	None	None	Neuropathy	None	Central	None	Yes	Yes	Yes	Complete
302	Device	2	Yes	None	None	None	None	Central Processing	None	None	None	No	No	No	Complete
303	Device	3	Yes	None	None	Inactive	None	Cerebellar Degeneration	None	Central	None	No	No	No	Complete
304	Device	4	Yes	None	Yes	None	None	Central Processing	None	Perpherial	None	No	No	Yes	Complete
305	Device	2	Yes	None	None	None	None	None	None	Perpherial	None	No	No	No	Withdraw: UnrelatedSurg
307	Device	3	None	Yes	None	None	None	Conductive	None	Perpherial	None	No	No	No	Complete
308	Device	3	None	None	None	None	None	Central Processing	None	Central	None	No	No	Yes	Complete
309	Device	4	Yes	None	Yes	None	None	Neuropathy	None	Central	None	No	No	No	Complete
310	Device	2	None	None	None	None	None	Brain Stem	None	Central	None	No	No	No	Complete
311	Device	3	Yes	None	Yes	None	None	Central Processing	None	None	None	No	No	No	Complete
401	On-site Control	4	Yes	None	None	Inactive	None	None	None	Central	TIA	No	No	No	SubjecDropped: TIA's
403	On-site Control	6	Yes	None	None	None	Non-specifi	None	Yes	Central	None	Yes	No	Yes	Withdraw:UnrelatedHospit
404	On-site Control	2	None	None	None	Inactive	None	Central Processing	None	None	None	No	No	No	Complete
405	On-site Control	3	None	Yes	None	None	None	Conductive	None	Central	None	No	No	No	Complete
407	On-site Control	1	Yes	None	None	None	None	None	None	Perpherial	None	No	No	No	Complete
408	On-site Control	3	Yes	None	Yes	None	None	None	None	Perpherial	None	No	No	No	Withdrew:Last appt illne
409	On-site Control	5	Yes	Yes	None	None	None	Central Processing	None	Perpherial	None	Yes	No	No	Complete
410	On-site Control	2	None	Yes	None	None	None	None	None	Central	None	No	No	No	DroppedMissedApptCardiac
411	On-site Control	5	Yes	None	Yes	None	None	Central Processing	None	Central	Stroke	No	No	No	Moved to St. Louis
412	On-site Control	3	Yes	None	None	None	None	None	None	Central	TIA	No	No	No	Complete

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